UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF MASSACHUSETTS

JOHN HANCOCK LIFE INSURANCE COMPANY, JOHN HANCOCK VARIABLE LIFE INSURANCE COMPANY, and MANULIFE INSURANCE COMPANY (f/k/a INVESTORS PARTNER LIFE INSURANCE COMPANY),	CIVIL ACTION NO. 05-11150-DPW
Plaintiffs,	
v.	
ABBOTT LABORATORIES,	
Defendant.	

NOTICE OF CORRECTION TO
AFFIDAVIT OF STEPHEN J. BLEWITT

Plaintiffs John Hancock Life Insurance Company, John Hancock Variable Life Insurance Company and Manulife Insurance Company (collectively, "John Hancock" or the "Plaintiffs"), respectfully submit this Notice of Correction to Affidavit of Stephen J. Blewitt. Exhibits supporting Paragraphs 96(j), 96(l) and 96(s) were incorrectly identified, and incomplete or over-inclusive copies of PLs' CE, IB, and LJ were attached. A corrected copy of the Affidavit of Stephen J. Blewitt, along with the corrected exhibits, are attached hereto.

JOHN HANCOCK LIFE INSURANCE COMPANY, JOHN HANCOCK VARIABLE LIFE INSURANCE COMPANY and MANULIFE INSURANCE COMPANY

By their attorneys,

/s/ Stacy L. Blasberg

Brian A. Davis (BBO No. 546462)
Joseph H. Zwicker (BBO No. 560219)
Richard C. Abati (BBO No. 651037)
Stacy L. Blasberg (BBO No. 657420)
CHOATE, HALL & STEWART LLP
Two International Place
Boston, Massachusetts 02110
Tele: 617-248-5000

Date: March 2, 2008

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on March 2, 2008.

/s/ Stacy L. Blasberg
Stacy L. Blasberg

4305917.1

UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF MASSACHUSETTS

JOHN HANCOCK LIFE INSURANCE COMPANY, JOHN HANCOCK VARIABLE LIFE INSURANCE COMPANY, and MANULIFE INSURANCE COMPANY (f/k/a INVESTORS PARTNER LIFE INSURANCE COMPANY),	CIVIL ACTION NO. 05-11150-DPW
Plaintiffs,	
v.	
ABBOTT LABORATORIES,	
Defendant.	

AFFIDAVIT OF STEPHEN J. BLEWITT

I, Stephen J. Blewitt, hereby state under oath that:

1. My name is Stephen J. Blewitt. I reside in Reading, Massachusetts.

2. I am a Senior Managing Director of plaintiff John Hancock's Bond and Corporate Finance Group ("BCFG"). I have been called to testify in this action concerning my involvement in negotiating, evaluating and administering the written "Research Funding Agreement" that John Hancock entered into with defendant Abbott Laboratories ("Abbott") on March 13, 2001 (the "Research Funding Agreement" or the "Agreement"). This affidavit sets forth my direct trial testimony.

3. I previously have submitted affidavits to this Court both in this action and in the prior, related action titled John Hancock Life Insurance Company, *et al.* v. Abbott Laboratories, Civil Action No. 03-12501-DPW ("Hancock I"). For the convenience of the Court, I have repeated the relevant portions of those documents in this affidavit.

The Parties and My Background

4. Plaintiff John Hancock Life Insurance Company is a company, duly formed and existing under the laws of the Commonwealth of Massachusetts, that provides various insurance and investment products to retail and institutional customers. John Hancock Life Insurance Company also is an investor in a diversified portfolio of investments, including commercial loans, corporate bonds, public and private securities and various other types of investment vehicles. John Hancock's investments are intended, *inter alia*, to ensure that the company generates a sufficiently stable stream of income to meet John Hancock's payment obligations to its policy holders, shareholders, and investors.

5. Plaintiff John Hancock Variable Life Insurance Company ("JHVL") is an affiliated company of John Hancock Life Insurance Company, duly formed and existing under the laws of the Commonwealth of Massachusetts. JHVL provides variable life insurance products that link life insurance coverage and an investment return to an underlying portfolio of investments selected by the policyholder.

6. Plaintiff Manulife Insurance Company ("Manulife") is an insurance company duly formed and existing under the laws of the State of Delaware. Prior to approximately February 2005, Manulife was known as "Investors Partner Life Insurance Company." Manulife is a wholly-owned subsidiary of JHVL that sells various types of life insurance products.

7. Unless otherwise indicated, plaintiffs John Hancock Life Insurance Company, JHVL and Manulife are collectively referred to herein as "John Hancock" or "Hancock."

8. I attended the University of Chicago and graduated with a Bachelors Degree in Economics in 1982. I began work with John Hancock shortly after my graduation from the University of Chicago. While employed by John Hancock, I attended graduate school at Boston University, and ultimately obtained a Masters Degree in Business Administration from Boston University in 1987.

9. My first position with John Hancock was in Hancock's Group Pensions Department. In 1988, I joined Hancock's BCFG, which serves as the primary fixed income asset manager for John Hancock, as well as for various third parties. I started with the BCFG as an Investment Officer and subsequently received a series of promotions within that group. As of 2000-2001, I was a Managing Director of John Hancock's BCFG. My duties included seeking out new, favorable investment opportunities for Hancock. My immediate supervisor in that time frame was Roger Nastou.

John Hancock's Prior Investments in the Pharmaceutical Industry

10. Prior to 2000, John Hancock had made other investments in the pharmaceutical industry. Hancock's investments took different forms; some were equity investments and some were debt investments.

11. For example, in or around 1997, John Hancock made a $32 million equity investment in Metabolex, Inc. ("Metabolex"), a company that focused on the discovery and development of new treatments for diabetes and related diseases. Abbott was another investor in Metabolex, and the terms of John Hancock's investment included the right to "put" or require Abbott to buy out Hancock's interest at a later time. The proceeds from Hancock's

investment were used by Metabolex to help fund research and development of a combined Abbott/Metabolex drug discovery program over a three year period.

12. I was a Senior Investment Officer for John Hancock on the Metabolex transaction. As part of the transaction, Metabolex was required to make certain representations and warranties to John Hancock. I and others at John Hancock also performed some targeted due diligence with respect to the potential markets for new diabetes treatments prior to recommending the Metabolex investment. Our work included a general analysis of the overall market using various industry research reports. We also engaged a scientific consultant (Dr. Allan Haberman) to provide additional independent scientific input and analysis.

13. John Hancock's investment in Metabolex was a successful one. Hancock eventually exercised its right to "put" its investment to Abbott for a gain.

14. In or about 1999, John Hancock made a $5 million equity investment in Idun Pharmaceuticals, Inc. ("Idun"), a company that focused on the discovery and development of small molecule cancer therapeutics targeting the biological pathways that control "apoptosis," or programmed cell death. Prior to 1999, Idun had entered into an exclusive scientific collaboration in the field of apoptosis with Abbott, which also was an equity investor in Idun. The proceeds from Hancock's investment were used by Idun for working capital and general corporate purposes, including funding continued research and development work.

15. I was a Senior Investment Officer for John Hancock on the Idun transaction. As part of the transaction, Idun was required to make certain representations and warranties to John Hancock. Once again, I and others at John Hancock also performed some targeted due diligence with respect to the potential markets for new cancer drugs prior to recommending the Idun investment. Our work included an analysis of the overall market for cancer therapies

based upon various industry research reports. We also engaged two scientific consultants (Dr. Jay George and Dr. Lynn Klotz) to provide additional independent input regarding the market for cancer drugs and emerging cancer therapies.

16. Pfizer eventually purchased Idun for almost $300 million dollars.

17. All told, John Hancock made investments totaling more than $180 million in a series of pharmaceutical or pharmaceutical-related entities prior to 2000, including Metabolex, Idun and various other entities such as Purdue Pharma, L.P., Celegene Corporation, Elan Pharmaceutical Investments Ltd., and Pharma Marketing Ltd. In each instance, John Hancock requested and received representations and warranties regarding the investment; in each instance, John Hancock personnel performed targeted due diligence concerning the products and/or the potential markets.

The Negotiation of the Research Funding Agreement

18. The negotiations between John Hancock and Abbott that ultimately resulted in the Research Funding Agreement that forms the basis of this action began sometime in or around late 1999. I am the person at John Hancock who had primary responsibility for evaluating, negotiating and administering that investment on Hancock's behalf.

19. Prior to the commencement of negotiations concerning the Research Funding Agreement, I had developed a business relationship with Philip Deemer, then the Director of Abbott's Corporate Licensing Department, as a result of John Hancock's prior joint investments with Abbott in Metabolex and Idun. Mr. Deemer and I periodically spoke with one another. Our discussions eventually focused on a potential investment by John Hancock in a selected portfolio of pharmaceutical compounds being developed by Abbott. At some point

in time, Stephen Cohen, then the Controller for Abbott's Pharmaceutical Research and Development Division, became involved in the discussions as well.

20. I was not the only person at John Hancock involved in the development, evaluation and approval of the proposed deal with Abbott. I was assisted at various times by, among others, Scott Hartz, who then was a Managing Director and Head Portfolio Manager in the BCFG, as well as by Shannon Walsh, a Portfolio Analyst.

21. As explained to me by Mr. Deemer, Abbott was interested in a potential funding agreement with John Hancock, in part, because it offered Abbott the opportunity to supplement its internal research and development budget on what Abbott regarded as reasonably attractive financial terms. I, in turn, was seeking an investment opportunity that would provide above-average returns on a portion of John Hancock's total investment portfolio with a reasonable level of risk.

22. Over time, Mr. Deemer, Mr. Cohen and I began to concentrate our discussions on an investment structure whereby John Hancock would invest approximately $50 million per year over a four-year period to fund the development of a specified "basket" of pharmaceutical compounds in Abbott's then current research and development portfolio. Abbott, in turn, would compensate John Hancock for its investment through a series of milestone and royalty payments that would become due if and when the compounds were commercialized.

23. I understood during negotiations that John Hancock's ability to earn a return on its investment in the proposed basket of Abbott pharmaceutical compounds would depend on the eventual commercial success of those compounds. If some or all of the compounds failed or otherwise were unsuccessful, John Hancock's financial return would be significantly diminished or eliminated entirely.

24. With these considerations in mind, I expressly notified Mr. Deemer during the negotiation of the Agreement that, from John Hancock's perspective, the structure of the proposed deal was highly dependent upon the number of pharmaceutical compounds included in the transaction, as well as the stage of development and expected sales of each compound. A true and accurate copy of an e-mail message that I sent to Mr. Deemer on the topic, dated March 7, 2000, is attached hereto as PLs' KP.

25. I specifically requested a diversified basket of compounds from Abbott reflecting a variety of therapeutic indications, stages of development, and expected sales in order to provide an acceptable return on John Hancock's proposed investment with a reasonable overall level of risk.

26. In or about mid-2000, I began working with various Abbott personnel, including Mr. Deemer, to identify a suitable basket of pharmaceutical compounds to include in the proposed deal, and to develop a mutually-acceptable royalty payment structure. Among the compounds proposed by Abbott for inclusion in the John Hancock basket were ABT-518, a Matrix Metalloproteinase Inhibitor (MMPI) for the treatment of cancer; ABT-594, a selective neuronal nicotinic (NNR) agonist for the treatment of chronic pain that just was commencing a Phase IIb clinical trial for diabetic neuropathic pain; ABT-773, one of a new class of powerful antibiotics known as "ketolides"; and ABT-980, a selective alpha blocker for the treatment of urinary tract blockages.

27. In negotiating John Hancock's Research Funding Agreement with Abbott, it was my intention to invest only in promising development candidates with positive commercial prospects. Neither I nor, based on my observations, anyone else at John Hancock intended to invest in compounds that Abbott knew or had reason to believe would be discontinued shortly.

28. I and my fellow investment professionals at John Hancock were in no position, however, to independently know the current status, prospects or plans for each of the deal compounds within Abbott's pharmaceutical R&D organization. That is why John Hancock required, with Abbott's agreement, that Abbott formally represent and warrant to Hancock the up-to-date status, condition and plans for the various compounds in the proposed basket of compounds. As set forth in an e-mail message that I sent to Mr. Cohen on July 7, 2000, specific information that John Hancock required in this regard included, among other things,

> [c]urrent status of clinical trials (i.e., what is current stage, what were results from prior stage or interim results – specifically, trial design and endpoints, discussions with FDA, Go/NoGo decision points). Potential labeling issues. Potential manufacturing issues. Timeline for completion of trials, NDA filing, [a]pproval. Commercialization rights and freedom to operate. Patent status.

A true and accurate copy of my e-mail to Mr. Cohen, dated July 7, 2000, is attached hereto as PLs' CI.

29. Abbott also agreed to provide to John Hancock information concerning Abbott's anticipated development spending on the proposed compounds in the form of projections and drafts of Abbott's first "Annual Research Plan" ("ARP"). True and accurate copies of various projections that Abbott provided to me in or about the fall of 2000 are attached hereto as PLs' PE and PO. I informed Mr. Deemer that Abbott's expected spending on the proposed compounds was important to John Hancock because I and others at Hancock regarded Abbott's own internal spending plans as a useful barometer of the commercial and technical prospects for the various compounds.

30. In response to John Hancock's requests, Mr. Deemer provided me, in or around June 2000, with a series of draft "Descriptive Memoranda" that included technical, financial

and other information for the compounds in Hancock's proposed basket of compounds. These materials were supplied to John Hancock by Abbott for the explicit purpose of permitting Hancock to understand and evaluate the proposed deal. True and accurate copies of the draft Descriptive Memoranda for ABT-518, ABT-594 and ABT-773 that Abbott provided to John Hancock in that timeframe are attached hereto as Ex. 1, and PLs' CC and HX.

31. Although the format of Abbott's individual Descriptive Memoranda varied somewhat, each Memorandum typically contained, in part: (a) a basic overview of the subject compound that described, among other things, the technical merits and development status of the compound, including the status and/or results of any clinical trials; (b) a discussion of the expected market for the compound, including the specific indications (*i.e.,* conditions or disease states) for which the compound was being developed by Abbott and estimates of the size of the U.S. and ex-U.S. commercial markets for each indication; (c) a description of the nature and severity of any known or suspected side effects and other important "considerations"; (d) an identification of any actual or potential competing products; and (e) a discussion of Abbott's current and future development plans for the compound. Each Descriptive Memorandum was clearly marked "Confidential" by Abbott.

32. At or around the time that Mr. Deemer provided me with the draft Descriptive Memoranda, I retained Dr. Lynn Klotz to assist me in evaluating the compounds that Abbott proposed to include in the deal. Dr. Klotz holds a Ph.D. in Chemistry and has substantial experience and knowledge concerning the pharmaceutical industry and medical issues.

33. I previously had retained Dr. Klotz to help evaluate John Hancock's proposed investment in Idun, and I found his research and analysis regarding the market for cancer

treatments to be very helpful in that context. I believe that I retained Dr. Klotz to evaluate another potential pharmaceutical investment in the same time frame.

34. I retained Dr. Klotz again in mid-2000, but not to comprehensively examine the science behind the compounds in Abbott's proposed basket of compounds. Rather, I retained him to review the descriptions and data contained in Abbott's Descriptive Memoranda and to verify, to the best of his ability using various available sources, the accuracy of the information that Abbott had supplied. Because Abbott had expressed a desire to close its proposed deal with John Hancock within the next few months, I asked Dr. Klotz to undertake and complete his work as soon as possible. A true and accurate copy of an e-mail message that Mr. Deemer sent to me on July 16, 2000, indicating Abbott's desire to move the deal forward promptly, is attached hereto as PLs' KV.

35. Dr. Klotz kept me apprised of his work by telephone and through a series of reports and updates that he sent to me in the months of June and July 2000. True and accurate copies of various reports and updates from Dr. Klotz are attached hereto as PLs' HY, KU, and KY.

36. I and others at John Hancock also employed the information provided by Abbott, in conjunction with general industry data obtained from other sources, to prepare a detailed "Monte Carlo" computer model that we used to develop projections and financial expectations for the proposed deal with Abbott. A Monte Carlo simulation generates numerous possible performance outcomes or scenarios that might occur in the future using a random number generator. It can be designed to account for the uncertainty and performance variation that is found in financial markets. The result of a Monte Carlo simulation is a

probability distribution of portfolio gains and losses that can be used to determine the value and the risk of a portfolio.

37. John Hancock's Monte Carlo simulation entailed running multiple projected scenarios that assessed each Program Compound's commercial and scientific risk profile in order to calculate a combined risk-assessment and expected rate-of-return on John Hancock's total investment, which information was used, in turn, by Hancock to determine what financial terms to demand in the Agreement, as well as whether to enter into the Agreement at all. I and other John Hancock personnel repeated the Monte Carlo simulation using updated data on numerous occasions while negotiations were underway. A true and accurate copy of an example of the output from one of John Hancock's early Monte Carlo simulations for the proposed deal with Abbott is attached hereto as PLs' KQ.

38. Specific data that John Hancock's Monte Carlo simulation considered and analyzed included, among other things: (a) the number of compounds in Hancock's proposed basket; (b) the likelihood that each compound actually would be fully developed by Abbott and obtain regulatory approval; (c) the anticipated commercial launch date for each compound; (d) likely peak and total sales for each compound once launched; (e) anticipated royalty rates; (f) estimates of the milestone and royalty payments that Hancock was likely to receive on both an annual and an aggregate basis; (g) Hancock's estimated risk of loss on the transaction; and (h) Hancock's estimated annual rate of return on the transaction.

39. In many instances, John Hancock's Monte Carlo simulation incorporated more conservative projections than those provided by Abbott in the draft Descriptive Memoranda and other materials provided to Hancock by Abbott, including lower peak sales projections for the proposed compounds.

40. The results of John Hancock's Monte Carlo simulation indicated that, assuming the underlying data concerning the condition of, and prospects for, the compounds was reasonably accurate, the proposed deal could be expected to generate average annual returns to Hancock in the range of approximately eighteen to twenty-two percent (18-22%), with a risk of total loss of approximately one to two percent (1-2%). These values were acceptable to me and caused me to continue to pursue the proposed transaction with Abbott. Under our method of analysis, however, the elimination of even a single compound from the basket would have had a significant, adverse impact on the results of the analysis and the attractiveness of the deal from my perspective and, I believe, from the perspective of John Hancock's management.

41. I notified Abbott during negotiations of John Hancock's expected returns on its investment with Abbott. On March 7, 2000, I forwarded to Mr. Deemer and Mr. Cohen a draft Summary of Terms. In my accompanying e-mail message, I stated, in part, that,

> [w]e believe that a diversified basket of compounds should yield the investor an IRR of 20-25%. Based on your desire to reduce the cost of capital and our desire to lower our risk, we have built in milestone payments, a tiered royalty structure, and a termination date for the royalties. The model provides us with an expected yield of 18-22%.

A true and accurate copy of my e-mail to Mr. Deemer and Mr. Cohen and attached Summary of Proposed Terms, dated March 7, 2000, is attached hereto as PLs' KP.

42. After Dr. Klotz had completed his independent research in mid-July 2000, he and I participated in a telephone interview of Dr. John Leonard of Abbott on or about July 28, 2000, during which Dr. Klotz asked Dr. Leonard, Abbott's Vice President of Development, a series of questions concerning the various proposed compounds. Mr. Deemer and Mr. Cohen also participated in that telephone interview. Dr. Klotz took notes of Dr. Leonard's responses

to each question during the telephone conference and prepared a written summary of his responses shortly thereafter. A true and accurate copy of that interview summary with Dr. Klotz's cover e-mail message to me, dated July 28, 2000, is attached hereto as PLs' KY.

43. During the course of the interview, Dr. Klotz specifically questioned Dr. Leonard about, among other things, the potentially small therapeutic window (*i.e.*, the ratio between the minimum dosage necessary to treat the indicated disease effectively and the maximum safe or tolerable dosage) of ABT-594, and asked him whether Abbott regarded it as acceptable. As I recall, Dr. Leonard responded in part by stating, in words or in substance, that when Abbott gave patients the "upper-limit dose" of ABT-594, "the side-effects aren't dangerous: headache, vomiting," and that these "minor side effects" appeared "to go away over time."

44. Based on his independent review of the publicly-available literature, his discussions with various researchers and physicians, and our telephone interview with Dr. Leonard, Dr. Klotz informed me in late July 2000 that, as best he could tell, there was "no indication of any deception on Abbott's part" with respect to the information provided in Abbott's draft Descriptive Memoranda, and that he did not see any reason for John Hancock not to move forward with its proposed investment in those compounds. Dr. Klotz's e-mail message to me containing his recommendation is included in PLs' KY.

45. I understood that Dr. Klotz remained available to further consult with me regarding John Hancock's proposed deal with Abbott after July 2000. I did not ask Dr. Klotz to do so, however, because I did not become aware of any new information from Abbott after that date that I believed required Dr. Klotz's further review or analysis.

46. Negotiations over the specific terms of the proposed Agreement between John Hancock and Abbott continued into the fall of 2000. John Hancock was represented in those negotiations by me, by attorneys W. Brewster Lee and Kevin Tormey of the law firm of Choate, Hall & Stewart in Boston, and by one of John Hancock's in-house attorneys, Amy Weed. Abbott was represented by Mr. Deemer and by its in-house attorneys, Daphne Pals and Brian Smith. Abbott prepared the first draft of the Research Funding Agreement, which Mr. Deemer forwarded to me on August 17, 2000. A true and accurate copy of an e-mail to me from Mr. Deemer with the first draft attached, dated August 17, 2000, is attached hereto as PLs' LC. A true and accurate copy of an example of another draft Agreement that was exchanged between the parties in October 2000 is attached hereto as PLs' LI.

47. By September 2000, the basic terms of the proposed transaction with Abbott had solidified to the point that it was possible to submit the deal to John Hancock's management for approval in concept. John Hancock's internal procedures at the time required the approval of Hancock's Bond Investment Committee, as well as its Committee of Finance, before a deal of the size that we were considering with Abbott could be finalized.

48. In September 2000, I prepared a report summarizing the proposed terms and the business rationale for the contemplated deal with Abbott (referred to internally and in this affidavit as a "Yellow Report") for submission to John Hancock's Bond Investment Committee and to the Committee of Finance. According to John Hancock standard practices at the time, the Yellow Report served as the principal, if not the only, document that Hancock's Bond Investment Committee and Committee of Finance reviewed in considering the Abbott transaction. A true and accurate copy of that Yellow Report, dated September 21, 2000, is attached hereto as PLs' LF.

49. I drafted the Yellow Report with the assistance and input of Mr. Hartz in reliance, to a large extent, on the information concerning the compounds that John Hancock had received from Abbott, on our Monte Carlo simulation, on the evaluation performed by Dr. Klotz, and on information obtained from various publicly-available sources. I believed at the time that the information contained in the Yellow Report was reasonably accurate, and that the assumptions and projections included in the Yellow Report were realistic and reasonably conservative.

50. The Yellow Report for the proposed Abbott transaction states, in part, that,

> [w]e are recommending a $220 million commitment to fund research and development expenses for a basket of eight pharmaceutical products ("Program Compounds") currently under development by Abbott Laboratories ("Abbott")....
>
> The Program Compounds are a diversified pool of eight compounds owned by Abbott Laboratories and in various stages of clinical development. The Compounds are divided between late-stage and early-stage, including three Phase III, two Phase II, one Phase I, and two pre-clinical compounds. The compounds are well-diversified from a disease/stage perspective, although several compounds are focused on the cancer market.... During the term of the transaction, we expect Abbott to spend approximately $1.3 billion (including John Hancock's commitment) on further research and development for the Compounds.
>
> Through the management fee and anticipated milestone payments, we expect to generate at least an 8% return on investment during the initial four years of the transaction. The average return is approximately 17.5% over 15 years. If we assume that we could sell our future royalty stream after the fifth year, our average five-year IRR would be about 22%.
>
> The transaction is structured to provide a one-to-two percent probability of total loss combined with a one-to-two percent chance of not earning a return. This is approximately equivalent to a 60 basis point annual loss over five years – or a "Ba1" credit

> rating. The expected return of 17.50% is attractive relative to the risk of the transaction.

51. I presented the proposed Abbott transaction to John Hancock's Bond Investment Committee on September 21, 2000. In the course of the presentation, I was asked various questions concerning the proposed structure of the transaction, the risk of the transaction, and the expected return for John Hancock on the transaction. The Bond Investment Committee ultimately voted to approve the deal based on, and as recommended in, the Yellow Report.

52. Roger Nastou, then the head of John Hancock's Bond and Corporate Finance Department, subsequently presented the Yellow Report for the proposed Abbott transaction to Hancock's Committee of Finance on October 10, 2000. After some discussion, the Committee of Finance also voted to approve the deal based on, and as recommended in, the Yellow Report. A true and accurate copy of the relevant minutes of the Committee of Finance, dated October 10, 2000, is attached hereto as PLs' LG.

53. Having obtained approval for the proposed transaction with Abbott from John Hancock's Bond Investment Committee and Committee of Finance, I and the others working on the deal were able to go forward with finalizing the terms of the deal and getting it executed. That process, however, took considerably longer than I had anticipated due to a variety of events.

54. One principal reason for the delay was Abbott's decision in the fall of 2000 to terminate the development of ABT-980, one of the compounds in John Hancock's planned basket of compounds. Mr. Deemer informed me that Abbott had decided to discontinue the development of ABT-980 in late October 2000. A true and accurate copy of an e-mail from

Mr. Deemer to me discussing Abbott's decision, dated October 27, 2000, is attached hereto as PLs' LJ.

55. The news regarding ABT-980 caused me considerable concern. The elimination of just that one compound from the portfolio materially altered the economics and attractiveness of the proposed deal from John Hancock's perspective. It reduced John Hancock's expected return and increased Hancock's risk of total loss. In light of the changes resulting from Abbott's decision to terminate ABT-980, I informed Mr. Deemer that John Hancock no longer was willing to proceed with the contemplated Agreement on the terms then proposed.

56. Rather than abandoning the proposed transaction entirely, however, the parties attempted to compensate for the loss of ABT-980 by significantly altering, among other things, the timing and amount of Hancock's proposed investment, as well as the milestones that would trigger Hancock's payment obligations. A true and accurate copy of a proposed draft Agreement incorporating the revised deal structure and terms, dated November 16, 2000, is attached hereto as PLs' LL. Several draft agreements incorporating the modified deal structure were exchanged between the parties in November and December 2000.

57. In or around December 2000, I was told by Mr. Deemer that Abbott's management wished to put its proposed transaction with John Hancock "on hold" because they were preoccupied with Abbott's recent acquisition of Knoll Pharmaceuticals ("Knoll"). I since have learned from documents produced by Abbott in this litigation that Abbott actually put the proposed transaction with John Hancock "on hold" in late 2000 because Abbott's management was "less enthusiastic about moving forward due to the new deal structure," and that Abbott's management simply "want[ed] to postpone a final decision until the new year." A copy of an

internal memorandum to that effect from Mr. Deemer to Arthur Higgins, then the President of Abbott's Pharmaceutical Products Division, dated December 1, 2000, is attached hereto as PLs' LO.

58. In or about mid-January 2001, I was notified that Abbott's management wished to proceed with the proposed transaction on the terms that existed as of October 2000, and that Abbott was willing to compensate John Hancock for the loss of ABT-980 by adding additional compounds to the planned basket of compounds.

59. I reviewed several new compounds that Abbott proposed to add to John Hancock's basket of compounds. One of the compounds that Abbott proposed to provide as a replacement for ABT-980 was ABT-822, a bimoclomol compound for the treatment of diabetes. I promptly reviewed the available information concerning bimoclomol compounds and concluded that they were not sufficiently promising to warrant an investment by John Hancock. Accordingly, I declined Abbott's offer to replace ABT-980 in the proposed Agreement with ABT-822.

60. Two additional compounds that Abbott proposed to add in place of ABT-980 were ABT-510 and ABT-492. I was provided with information on each compound by Abbott. I reviewed the information from Abbott and other available information on the compounds and determined that ABT-510, a cytotoxic compound intended to inhibit the growth of new blood vessels in cancerous tumors, was similar to some of the cancer therapies that Drs. Klotz and George previously had evaluated at my request for the Idun deal. Based on my existing knowledge of the market for such therapies and the fact that the proposed Agreement with Abbott provided that Hancock would receive a replacement compound if the first of ABT-510

and ABT-492 did not progress in clinical trials, I did not perceive a need to reengage Dr. Klotz to evaluate that compound.

61. My research further disclosed that ABT-492 was an anti-infective agent that Abbott recently had in-licensed from Wakunaga Pharmaceutical Co., Ltd. ("Wakunaga"), a Japanese pharmaceutical company. I was comfortable at the time that Abbott would not have in-licensed ABT-492 from Wakunaga if Abbott did not actually believe that ABT-492 had reasonable prospects for success. Additionally, the proposed Agreement with Abbott provided that John Hancock would receive a replacement compound if the first of ABT-510 and ABT-492 did not progress in clinical trials. Accordingly, I did not see a need to reengage Dr. Klotz to evaluate that compound.

62. After reviewing the information regarding ABT-510 and ABT-492, and confirming that the inclusion of those compounds, in addition to certain other changes in John Hancock's proposed payments and the milestone and royalty payments proposed to be made by Abbott, in John Hancock's Monte Carlo simulation model resulted in a sufficiently improved rate of return and reduced level of risk, John Hancock accepted Abbott's proposal to replace ABT-980 in or about early February 2001.

63. At the same time, I recall expressing concern to Abbott that, with the addition of ABT-510, John Hancock's planned "diverse" basket of compounds was becoming overly-concentrated on potential cancer therapies. As a solution, Abbott proposed, and I agreed, to remove Abbott's pre-clinical "Urokinase Program" from the proposed basket and replace it with Abbott's pre-clinical "Erectile Dysfunction" or "ED Program." Abbott further agreed that, if the initial compound that emerged from its ED Program failed to proceed past Phase I, Abbott would replace that failed compound with the next Phase I compound to emerge from its

ED Program. Abbott's agreement on this point, plus my own review of the available information, gave me sufficient confidence to add the pre-clinical ED Program to the basket of compounds in place of the Urokinase Program without additional input from Dr. Klotz.

64. Abbott and John Hancock thereafter continued to modify and refine the terms of their proposed Research Funding Agreement in various ways, but the group of nine "Program Compounds" encompassed by that Agreement remained unaltered through the Agreement's execution on March 13, 2001.

The Final Agreement

65. The final Agreement between John Hancock and Abbott was executed by me and Dr. Jeffrey Leiden, then Executive Vice President of Abbott's Pharmaceuticals Division and its Chief Scientific Officer, on March 13, 2001. A true and accurate copy of the executed Agreement, dated March 13, 2001, is attached hereto as Ex. 32.

66. On March 12, 2001 (*i.e.*, the day before the Research Funding Agreement was executed), I received another e-mail message from Mr. Deemer in which he expressly assured me that Dr. John Leonard, Abbott's Vice President of Development, had "looked at all of the documents one last time in preparation for execution" and noted just "one oversight on one of the Programs"; a delay in the commencement of Abbott's Phase I study of ABT-518, which "was to have started on December 2000 (4Q2000) but in fact did not start until earlier this month" (*i.e.*, March 2001). Mr. Deemer further informed me that, although the delay in the commencement of Abbott's Phase I trial of ABT-518 "pushed the timeline [for that compound] back by a quarter throughout," Abbott's estimated "launch date" for ABT-518 was "not affected and is actually planned one quarter earlier." He attributed Abbott's delay in "starting some of these earlier compound studies" to delays in "completing this financing and hence the

reason this one got pushed back a little." A true and accurate copy of Mr. Deemer's e-mail message to me, dated March 12, 2001, is attached hereto as PLs' R.

67. I understood, at the time that I received Mr. Deemer's e-mail message on March 12, 2001, that he was updating me on the condition of, and the prospects for, the Program Compounds pursuant to Abbott's obligations under Section 12.2(m) of the final Agreement, in which Abbott expressly represented and warranted to Hancock that,

> [w]ith respect to each Program Compound, since the date of its respective Compound Report, to the knowledge of Abbott, no condition, circumstance or fact has arisen (other than generally available information concerning the pharmaceutical industry in general) nor has Abbott made any change in the conduct of the Research Program which, individually or in the aggregate, has resulted in, or could reasonably be expect[ed] to result in, a material adverse effect on the prospects or condition (including safety, efficacy, scientific viability or commercial [viability]) of such Program Compounds.

68. The news that Abbott's Phase I trial of ABT-518 had been delayed a few months did not concern me in any material way, particularly in light of Mr. Deemer's simultaneous representation that Abbott actually intended to commercialize that compound three months earlier than previously disclosed. Of much greater significance to me was the fact that neither Mr. Deemer, nor Dr. Leonard identified, on March 12, 2001, any other material change in the condition of, prospects for, or Abbott's plans for, any of the Program Compounds. I regarded their silence in this regard as confirmation by Abbott, pursuant to the terms of the Agreement, that no other such change had taken place, and that there was no reason for John Hancock not to proceed with the Agreement.

69. From the time that I received Mr. Deemer's e-mail message on March 12, 2001, up until the execution of the Agreement the following day, no additional changes,

concerns, discrepancies or errors in the documentation regarding the various Program Compounds were disclosed to me or, based on my observations, to anyone else at John Hancock by Abbott.

70. The terms of the final Agreement that was signed on March 13, 2001 call for John Hancock to invest up to $214 million over four years in the development of nine Program Compounds including, but not limited to, ABT-518, ABT-594 and ABT-773.

71. Under the terms of the Agreement, John Hancock's ability to earn a return on its investment in the Program Compounds depends on the commercial success of those compounds. If some or all of the compounds fail or otherwise are unsuccessful, Hancock's financial return is reduced accordingly.

72. Similarly, because John Hancock only shares in the revenues, if any, generated by the Program Compounds for a set number of years, Hancock stands to gain more if the Program Compounds are developed quickly.

73. The final Descriptive Memoranda (also referred to in the Agreement as "Compound Reports") were attached to, and incorporated in, the Agreement as collective Exhibit 12.2(i). Abbott's purported spending plans as of the date of the Agreement were contained in its first ARP, which was attached to, and incorporated in, the Agreement as Exhibit 1.6.

74. Abbott expressly represented and warranted both the completeness and the accuracy of the information contained in its Descriptive Memoranda and in its first ARP in Article 12 of the Agreement. More specifically, Abbott represented and warranted to John Hancock in Section 12.2(i) that,

> [n]either this Agreement nor any Exhibit to this Agreement (including the compound reports attached as Exhibit 12.2(i) hereto (the "Compound Reports")) contains any untrue statement of material fact or omits to state any material fact necessary to make the statements contained therein not misleading. There is no fact known to Abbott (other than generally available information concerning the pharmaceutical industry in general) as of the date of this Agreement that has not been disclosed in this Agreement or any Exhibit to this Agreement which has resulted in, or could reasonably be expected to result in, a material adverse effect on the prospects or condition (including safety, efficacy, scientific viability or commercial [viability]) of the Research Program or any of the Program Compounds.

75. I and, based on my observations, others at John Hancock actually relied upon various express representations made by Abbott in the Agreement, including the representations contained in Sections 12.2(i) and 12.2(m), in the Descriptive Memoranda, and in Abbott's first ARP, in deciding to enter into the Agreement on March 13, 2001 on the terms stated.

76. I regarded, and continue to regard, the representations made by Abbott in Sections 12.2(i) and 12.2(m) of the Agreement, in the Descriptive Memoranda, and in Abbott's first ARP, among others, as material to John Hancock's decision to enter into the Agreement on March 13, 2001 on the terms stated. I would not have recommended that John Hancock enter into the Agreement if Abbott had not agreed to provide Hancock with those representations and warranties.

Abbott's Misrepresentations and Fraud Regarding the Actual Status and Prospects of the Program Compounds as of the Date of the Agreement

77. Since I executed the Research Funding Agreement on John Hancock's behalf on March 13, 2001, I have come to learn that the actual status and prospects of at least three of the Program Compounds, ABT-518, ABT-594 and ABT-773, were materially different from what Abbott represented to Hancock in that Agreement. I also have come to learn that

Abbott's actual plans for at least two of the Program Compounds, ABT-518 and ABT-594, as of March 13, 2001, were materially different from what Abbott represented to John Hancock in the Agreement. The true facts, as I now understand them, include the following.

ABT-518

78. Over the approximately ten months of active contract negotiations leading up to the execution of the Research Funding Agreement, Abbott supplied me and others at John Hancock with three versions of its Descriptive Memorandum for ABT-518 and/or Abbott's "MMPI Program": an initial draft dated May 31, 2000; and updated draft dated November 1, 2000; and the final version dated February 2001. True and accurate copies of Abbott's draft Descriptive Memoranda for ABT-518 are attached hereto as Ex. 1 and 2. Abbott's final Descriptive Memorandum for ABT-518 forms a part of collective Exhibit 12.2(i) to the Agreement, which is attached hereto as Ex. 32.

79. Each version of Abbott's Descriptive Memorandum for ABT-518 states, among other things, that:

(a) "Abbott's Matrix Metalloproteinase Inhibitor (MMPI) program represents a novel therapeutic class, with the potential to alter the way cancer is treated by preventing or modifying disease progression and/or metastases";

(b) "The MMPI selectivity profile exhibited by ABT-518 distinguishes it from competitor's compounds"; and

(c) "ABT-518 is therefore a compelling development candidate with the potential to demonstrate antitumor effects superior to the [other] MMPI inhibitors currently undergoing clinical trials." Abbott further

> represented that "Phase I clinical trials" of ABT-518 by Abbott "began March 2001," and that "[c]linical studies across a wide range of solid tumors will be initiated…."

80. The various versions of Abbott's Descriptive Memorandum for ABT-518 also consistently identify other "MMPIs in Clinical Development for Cancer" as including "Marimistat" [*sic*], which reportedly was being developed by British Biotechnology and Schering Plough, and "Prinomastat," which reportedly was being developed by a combination of Agouron Pharmaceuticals, Warner Lambert and Pfizer.

81. With respect to these competing MMPI compounds, each version of Abbott's Descriptive Memorandum states that,

> [a]lthough Abbott's timing to market is not optimal, the shortcomings of the competitive products provide an opportunity for a compound with an improved SE or efficacy profile. Current animal models seem to predict Abbott's compound [i.e., ABT-518] is superior to those currently in clinical trials, and has the potential to be best in class.

82. Prior to the execution of the Agreement, Abbott never wavered in its representations to me and to others at John Hancock that Abbott considered ABT-518 to be a "compelling development candidate" that had "the potential to be best in class" among a "novel therapeutic class" of similar compounds being developed by a range of pharmaceutical companies.

83. Since the execution of the Research Funding Agreement, I have learned that Abbott's express representation in the Agreement that Abbott believed ABT-518 to be a "compelling development candidate" as of March 13, 2001, as well as various other representations that Abbott made to Hancock in the Agreement regarding the purported

prospects and condition of ABT-518, were materially false and/or incomplete. Material facts that Abbott either misrepresented or failed to disclose to me or to others at John Hancock include the following:

(a) Contrary to the representations made by Abbott in its Descriptive Memorandum for ABT-518, Abbott knew before the Agreement was signed that other pharmaceutical companies had dramatically curtailed or discontinued their own MMPI programs. Members of Abbott's management were aware no later than February 2001 that Agouron Pharmaceuticals and Pfizer had announced the prior summer that they were "stopping Phase III trials of Prinomastat in advanced prostate [cancer] and NSCLC [non-small cell lung cancer] because 'primary efficacy objectives were not met,'" and that "Marimastat development was discontinued" by British Biotech on February 15, 2001; (*See* PLs' I attached);

(b) Less than one week prior to the execution of the Agreement, the senior management of Abbott's Pharmaceuticals Division -- led by Dr. Leiden and including Dr. Leonard -- reviewed ABT-518's current status and prospects as part of the comprehensive Initial Portfolio Prioritization Review that they conducted on March 7-9, 2001. Questions were raised about ABT-518 during the course of the review in light of the information that several competitor MMPIs already had been discontinued; (*See* PLs' M, N, BL, EZ attached);

(c) Shortly after the presentation and discussion concerning ABT-518, Dr. Leiden, in his capacity as Executive Vice President of Abbott's Pharmaceuticals Division and its Chief Scientific Officer, ordered an immediate halt to all

expenditures on the development of ABT-518 due to his concerns about the low prospects of success for that compound; (*See* PLs' X, BL, FH, PH, PJ, PT attached);

(d) Consistent with the decision made at Abbott's Initial Portfolio Prioritization Review in early March 2001, Abbott personnel working on ABT-518 were instructed by their superiors on Sunday, March 11, 2001 (*i.e.*, two days before the Agreement was executed), to "stop all development activities immediately." I understand that Dr. Azmi Nabulsi, an Abbott employee who was working on the Phase I study of ABT-518 that Abbott recently had commenced in the Netherlands, notified his counterpart in Europe the same day that "we are not proceeding with the trial as a result of the [ABT-518] projects re-prioritization following the acquisition of Knoll"; (*See* PLs' X, BL, PJ attached);

(e) As a consequence of Abbott's order to stop all development activities on ABT-518 immediately because of the low prospects of success for that compound, further enrollment in the Phase I trial of ABT-518 was halted on or about March 12, 2001 (*i.e.*, the day before the Agreement was executed); (*See* PLs' T, X, Z, BL attached);

(f) When Mr. Deemer learned, just before the Agreement was signed, that Abbott's senior management had decided to halt further development of ABT-518, he contacted Dr. Leonard to remind him that ABT-518 was one of the Program Compounds in the planned John Hancock portfolio of compounds. Dr. Leonard, in turn, promptly spoke with Dr. Leiden, reminded him of the

impending Agreement with John Hancock, and suggested that Abbott proceed with the development of ABT-518; (*See* PLs' AB attached); and

(g) On March 13, 2001 (*i.e.*, the day the Agreement was executed), Dr. Leiden directed Abbott personnel to recommence the Phase I trial of ABT-518 and signed the Agreement on Abbott's behalf. (*See* Ex. 32 and PLs' V, X, BL attached).

84. I further understand that the Phase I trial of ABT-518 did not immediately recommence on March 13, 2001. It took Abbott personnel and the clinicians at the trial sites more than another week to resume patient enrollment in the trial. (*See* PLs' AC attached). I also understand that certain other development work on ABT-518, including various toxicology tests and analyses, never was resumed by Abbott after being halted, per Dr. Leiden's order, on or about March 12, 2001. (*See* PLs' AP attached).

85. None of the facts set forth in Paragraph 83 of this Affidavit was disclosed to me or, based on my observations, to others at John Hancock either in the Research Funding Agreement or otherwise before I executed that Agreement on Hancock's behalf.

86. The true prospects and condition of ABT-518 as of March 13, 2001 was information material to my decision and, based on my observations, the decision of others at John Hancock to recommend and to enter into the Agreement with Abbott on the terms stated therein.

87. Had Abbott informed me or others at John Hancock of the true prospects and condition of ABT-518 as of March 13, 2001, as set forth, *inter alia*, in Paragraph 83 of this Affidavit, that information would have significantly and adversely altered the economics and attractiveness of the proposed funding deal from my perspective. It would have reduced John

Hancock's expected return and increased Hancock's risk of total loss. I believe that, in such circumstances, I would not have recommended that John Hancock enter into the Agreement in its present form, and it is quite possible that I ultimately would not have recommended that Hancock enter into any funding agreement with Abbott at all.

88. For example, if Mr. Deemer or Dr. Leonard had notified me on or prior to March 13, 2001, that Dr. Leiden, in his capacity as Executive Vice President of Abbott's Pharmaceuticals Division and its Chief Scientific Officer, had ordered an immediate halt to all expenditures on the development of ABT-518 *just days before* due to Dr. Leiden's concerns about the low prospects of success for that compound, I am confident that I would not have signed the Agreement in its present form, which includes ABT-518, on that date. John Hancock had no interest in investing millions of dollars in compounds that already had been discontinued by Abbott, or that Abbott knew or had reason to believe would be discontinued shortly.

89. Had Abbott been more forthcoming regarding the actual condition of, and prospects for, ABT-518 on or prior to March 13, 2001, I believe that, at a minimum, the execution of the Research Funding Agreement would have been delayed for a period of weeks or months to allow the parties to renegotiate the terms of the Agreement to compensate John Hancock for the apparent or impending loss of ABT-518 from Hancock's portfolio of compounds.

90. If I had ceased to recommend that John Hancock enter into the proposed Agreement with Abbott at any time on or prior to March 13, 2001, on account of any actual or perceived problems concerning the condition of, or prospects for, ABT-518, I am confident that that Agreement would not have gone forward.

91. Abbott did not notify me or, based on my observations, anyone else at John Hancock of its final decision to terminate ABT-518 until September 20, 2001, at which time Abbott stated only that it had "refocused its efforts in cancer discovery and, as a result, has made the decision to terminate the MMPI Program, which includes Program Compound ABT-518." Abbott provided me with no additional information regarding the basis for, or the history of, its decision to terminate ABT-518 at that time. A true and accurate copy of Daphne Pals, Esq.'s letter to me notifying me of Abbott's final decision to terminate ABT-518, dated September 20, 2001, is attached hereto as Ex. 13.

ABT-594

92. Over the approximately ten months of active contract negotiations leading up to the execution of the Research Funding Agreement, Abbott supplied me and others at John Hancock with three versions of its Descriptive Memorandum for ABT-594: a initial draft dated April 2000; an updated draft dated November 2000; and a final draft, dated February 2001. True and accurate copies of the draft ABT-594 Descriptive Memorandum, dated April 2000, and the draft ABT-594 Descriptive Memorandum, dated November 2000, are attached hereto as PLs' CC and DL. Abbott's final Descriptive Memorandum for ABT-594 forms a part of collective Exhibit 12.2(i) to the Agreement, which is attached hereto as Ex. 32.

93. With minor variations, each version of Abbott's Descriptive Memorandum for ABT-594 describes that compound, among other things, as follows:

(a) "ABT-594 is a non-opioid, non-[steroidal anti-inflammatory drug] analgesic … that is 30 to 100-fold more potent and equally efficacious to morphine in several well-characterized animal models of pain";

(b) Abbott's "initial targeting indication [for ABT-594] is symptomatic treatment of diabetic neuropathic pain";

(c) "[t]he preclinical side effect and dependency liability profile of ABT-594 is superior to that of morphine";

(d) ABT-594 was "expected to be the first neuronal nicotinic receptor agonist to receive an indication for pain" and "has a novel mechanism of action and a potentially broad coverage of chronic pain conditions" in addition to "an opoid-like, efficacy without tolerance, dependence or abuse potential, while having equivalent/superior efficacy to other drugs used to treat neuropathic pain";

(e) a "phase IIb study for neuropathic pain at higher, titrated doses of ABT-594 began in April 2000 and ends in June 2001" with a "total of 320 patients anticipated to be included in the study";

(f) and a "[New Drug Application] filing" with the FDA for ABT-594 was "expected in 3Q2003."

94. Abbott simultaneously represented to me and to others at John Hancock in its first ARP that Abbott's "2001 Current Projection (Plan)" for spending on ABT-594 as of the date of the Agreement was "35.0" million dollars, including over $11.5 million for new Phase II and Phase III studies of the compound that Abbott purportedly planned to commence in Calendar Year 2001.

95. Prior to the execution of the Agreement, Abbott never wavered in its representations to me and to others at John Hancock that ABT-594 had "an opioid-like efficacy without tolerance, dependence or abuse potential," and that Abbott expected ABT-594 "to be the first neuronal nicotinic receptor agonist to receive an indication for pain."

96. Since the execution of the Research Funding Agreement, I have learned that Abbott's express representation in the Agreement that Abbott "expected" ABT-594 "to be the first neuronal nicotinic receptor agonist to receive an indication for pain" as of March 13, 2001, as well as various other representations that Abbott made to Hancock in the Agreement regarding the prospects and condition of ABT-594 and Abbott's expected spending on that compound, were materially false and/or incomplete. Material facts that Abbott either misrepresented or failed to disclose to me and to others at John Hancock include the following:

(a) Abbott's Phase IIb trial of ABT-594 for the treatment of diabetic neuropathic pain (known within Abbott as trial "M99-114") commenced in April 2000. The Phase IIb trial was designed to include 320 "subjects" or patients in a "double-blinded" format in order to achieve what Abbott perceived would be a statistically significant result. Almost immediately, Abbott's Phase IIb trial encountered problems with "premature terminations" (*i.e.*, subjects dropping out of the trial early) due primarily to "adverse events" ("AEs") or side effects among trial subjects including moderate-to-severe nausea, emesis (*i.e.*, vomiting) and dizziness; (*See* Ex. 16, 18 and PLs' CF, BY attached);

(b) By June 2000, Abbott's ABT-594 Product Development Team already was reviewing the available "strategic options" to address the slow enrollment of subjects in the trial. The premature termination and enrollment problems did not improve, however. As of July 7, 2000, of the 78 subjects who had entered Abbott's Phase IIb study of ABT-594, "at least" 31 had prematurely terminated their involvement in the study due to adverse events; (*See* PLs' CE, CJ, CK attached);

(c) By August 2000, there was "much concern with the drop out rate" in the Phase IIb trial among members of Abbott's ABT-594 Product Development Team; (*See* PLs' CN attached);

(d) Abbott continued to try various measures in the summer and fall of 2000 to address the premature termination and enrollment problems that it was encountering in its Phase IIb trial of ABT-594, including sending written surveys to the various clinical test sites to "examine AEs (nausea, vomiting, and dizziness)," and extending the enrollment deadline for the trial from September 22, 2000, to March 2, 2001. I understand that Abbott even investigated the possible use of one or more outside patient recruitment firms to assist in identifying and enrolling more subjects in the study. The patient recruitment firms that Abbott solicited (but not John Hancock) were informed, *inter alia*, that the Phase IIb study had a "[h]igh study dropout rate of 34% primarily due to side effects of the investigational drug"; (*See* PLs' CM, CR, CW, CZ attached);

(e) By the fall of 2000, members of Abbott's senior management regarded ABT-594 as having "questionable commercial viability"; (*See* PLs' CU, DT, PI attached);

(f) In mid-to-late 2000, Abbott employees with responsibility for supervising the Phase IIb trial of ABT-594 reviewed the preliminary, blinded trial data and concluded that the episodes of nausea and vomiting observed in the trial probably were dose-related. I understand that they considered, but ultimately rejected, revising the trial while it was underway to eliminate the highest dosage

(*i.e.*, 300 microgram) cohort in an effort to reduce the observed rate of nausea and vomiting; (*See* PLs' CJ, CK attached);

(g) In early December 2000, Abbott's management decided not to retain a patient recruitment firm for its Phase IIb study of ABT-594, concluding that doing so was not a "viable option at this time"; (*See* PLs' DJ, DV attached);

(h) Rather than continue to try to bolster patient enrollment in its Phase IIb trial of ABT-594, Abbott decided in December 2000 to prematurely terminate that trial as of January 5, 2001, a date that Abbott recognized was "2 months ahead of [its] most recent estimate of March 5, 2001" and would result in "less than [Abbott's] original target of 320 patients"; (*See* Ex. 20 and PLs' FZ attached);

(i) Enrollment in Abbott's Phase IIb study of ABT-594 actually was stopped on January 5, 2001, at 266 subjects; (*See* PLs' FZ attached);

(j) Abbott understood as of December 2000 that prematurely terminating its Phase IIb study of ABT-594 at less than 320 subjects would undermine the statistical validity of that study and render it effectively useless for advancing the further development of ABT-594; (*See* PLs' DW, DR attached);

(k) Abbott made the decision in early December 2000 to prematurely terminate its Phase IIb trial of ABT-594 based, in significant part, on the belief of Abbott personnel that the final results of that trial were likely to demonstrate that ABT-594 was not a viable commercial product;

(l) Abbott made what it described internally as "significant changes" in its developmental strategy for ABT-594 at or around the time that Abbott decided to prematurely terminate its Phase IIb trial of that compound. I understand that

those significant changes included Abbott's decision in late 2000 to explore a potential co-development partnership for ABT-594 with other pharmaceutical companies; (*See* PLs' DC, FZ attached);

(m) Abbott personnel were concerned, however, about the potential impact of disclosing what was described internally at Abbott as ABT-594's "nausea and vomiting issue" to possible co-development partners; (*See* PLs' DM attached);

(n) In the end, none of the pharmaceutical companies that Abbott approached in late 2000 or early 2001 concerning ABT-594 was willing to enter into a co-development agreement for that compound;

(o) At or around the same time that Abbott made significant changes in its developmental strategy for ABT-594 and began searching for a co-development partner for that compound, Abbott significantly reduced its planned spending on ABT-594 for Calendar Year 2001. Although Abbott continued to represent to me and to others at John Hancock in drafts and in the final version of its first ARP that it expected spending "35.0" million dollars on the development of ABT-594 in 2001, Abbott's actual planned spending on ABT-594 in 2001 had dropped, as of early March 2001, to approximately $9.3 million, a reduction of more than 73 percent; (*See* Ex. 32 and PLs' LW, MB, RX attached);

(p) Abbott's reduced spending for 2001 included enough funds to complete a "Go/No Go" decision regarding ABT-594 following the prematurely terminated Phase IIb trial, but did not include any funding for the previously planned additional Phase II or Phase III trials of that compound, which were described in

Abbott's internal 2001 Plan Final Reference Package as having been "Delayed"; (*See* PLs' LW, MB attached);

(q) Representatives of Abbott's ABT-594 Product Development Team made a presentation concerning ABT-594 to members of Abbott's senior management (including Dr. Leiden) on February 2, 2001. I understand that information concerning the prematurely terminated Phase IIb trial was included in the presentation. The presentation also included information about potential NNR "back-up" or "follow-on" compounds to ABT-594. I further understand that, at the conclusion of the presentation, Abbott's management recommended that Abbott personnel develop a "comprehensive strategy to address tolerability issues related to NNRs for pain, including ABT-594 and follow-ons"; (*See* PLs' EL, EN, EO attached);

(r) By February or early March 2001, Abbott scientific personnel who were charged with discovering and developing new NNR compounds had concluded that "ABT-594 … is an imperfect drug" due, in large part, to the "key adverse events of emesis, nausea, and dizziness that have consistently been observed during clinical evaluation of ABT-594"; (*See* PLs' EV, ES attached);

(s) Members of Abbott's senior management, including Drs. Leiden and Leonard, reviewed ABT-594 again in the course of Abbott's Initial Portfolio Prioritization Review on March 7-9, 2001. I understand that preliminary data from the recently discontinued Phase IIb trial of ABT-594 was discussed during the Initial Portfolio Prioritization Review, and concerns were expressed about the data; (*See* PLs' PT, EZ attached); and

(t) As part of, or shortly after, the Initial Portfolio Prioritization Review, members of Abbott's senior management, again including Dr. Leiden, met in executive session and discussed what they thought would be the likely outcome of the Phase IIb trial of ABT-594 and, ultimately, Abbott's development program for that compound. I understand that Abbott's senior management surmised that the Phase IIb trial outcome would be negative, with the result that they likely would terminate ABT-594. (*See* PLs' FH attached).

97. I understand that Abbott terminated the development of ABT-594 not long after the results of the Phase IIb neuropathic pain trial were officially unblinded in April 2001. I further understand that those results confirmed that each of the three dosages of ABT-594 tested in the study "Were Associated with a Dose Dependent Increase in Adverse Events, Especially Nausea, Vomiting and Dizziness," and that the resultant "Unfavorable Side Effect Profile" was sufficient to terminate the compound.

98. None of the facts set forth in Paragraph 96 of this Affidavit was disclosed to me or, based on my observations, to others at John Hancock either in the Research Funding Agreement or otherwise before I executed that Agreement on Hancock's behalf.

99. The true prospects and condition of ABT-594 as of March 13, 2001, as well as Abbott's expected spending on that compound, was information material to my decision and, based on my observations, the decision of others at John Hancock to recommend and to enter into the Agreement with Abbott on the terms stated therein.

100. Had Abbott informed me or others at John Hancock of the true prospects and condition of ABT-594 as of March 13, 2001, as set forth, *inter alia*, in Paragraph 96 of this Affidavit, that information would have significantly and adversely altered the economics and

attractiveness of the proposed funding deal from John Hancock's perspective. It would have dramatically reduced John Hancock's expected return and dramatically increased Hancock's risk of total loss. I believe that, in such circumstances, I would not have recommended entering into that Agreement in its present form or, more likely, that I ultimately would not have recommended that John Hancock enter into any funding agreement with Abbott at all.

101. For example, if Mr. Deemer or Dr. Leonard had notified me on or prior to March 13, 2001, that Abbott had prematurely terminated its Phase IIb trial of ABT-594 in early January 2001 at less than its target of 320 patients due to a large number of adverse events involving, among other things, moderate-to-severe nausea and vomiting, that Abbott had decided to reduce its own planned spending on that compound in Calendar Year 2001 by over seventy percent, or that Abbott's senior management had determined *just days before* that Abbott probably would terminate the development of ABT-594 when the final results of that Phase IIb trial were unblinded, I am confident that I would not have signed the present Agreement, which includes ABT-594, on that date. As previously stated, John Hancock had no interest in investing millions of dollars in compounds that already had been discontinued by Abbott, or that Abbott knew or had reason to believe would be discontinued shortly.

102. If I had ceased to recommend that John Hancock enter into the proposed Agreement with Abbott at any time on or prior to March 13, 2001, on account of any actual or perceived problems concerning the condition of, or prospects for, ABT-594, I am confident that that Agreement would not have gone forward.

103. Abbott did not notify me or, based on my observations, anyone else at John Hancock of its decision to terminate ABT-594 until November 16, 2001, at which time Abbott stated only that it had "decided to terminate further development of ABT-594 (a drug for the

treatment of neuropathic pain)." Abbott provided me with no additional information regarding the basis for, or the history of, its decision to terminate ABT-594 at that time. A true and accurate copy of Daphne Pals, Esq.'s letter to me notifying me of Abbott's final decision to terminate ABT-594 (with the handwritten notes of Abbott personnel), dated November 16, 2001, is attached hereto as PLs' GL.

ABT-773

104. Over the approximately ten months of active contract negotiations leading up to the execution of the Research Funding Agreement, Abbott supplied me and others at John Hancock with three versions of its Descriptive Memorandum for ABT-773: an initial draft dated June 5, 2000; an updated draft dated November 1, 2000; and the final version, dated February 2001. True and accurate copies of the draft ABT-773 Descriptive Memorandum, dated June 5, 2000, and the draft ABT-773 Descriptive Memorandum, dated November 1, 2000, are attached hereto as PLs' HX and IA. Abbott's final Descriptive Memorandum for ABT-773 forms a part of collective Exhibit 12.2(i) to the Agreement, which is attached hereto as Ex. 32.

105. Each version of Abbott's Descriptive Memoranda for ABT-773 states, among other things, that:

(a) "Product features such as high efficacy, activity against resistant strains of bacteria and convenience should enable [ABT-773] to compete against both Zithromax and newer agents such as quinolones";

(b) "[d]osing is expected to be once-a-day" and a "5-day convenience pack at a competitive price will help maximize sales"; and

(c) "[t]he likely profile of ABT-773 justifies further development [because] ABT-773 pertains to new class of antibiotics, good activity against resistant Gram+ organisms, particularly macrolide-resistant *S. pneumaniae*, convenience, safety and tolerability profile competitive with [Zithromax], and oral suspension and I.V. forms enabling penetration into pediatrics and hospital segments."

106. I understood as of 2000-2001 that Zithromax is a competing macrolide-based antibiotic that already was commercially available. I further understood, based on Abbott's statements, that Abbott believed Zithromax's tolerability had "redefined expectations for tolerability of new agents" and had "moved the market toward short course therapies dosed once daily."

107. I understood as of 2000-2001 that quinolones are yet another type of antibiotic with which ABT-773 potentially would compete.

108. Prior to the execution of the Agreement, Abbott never wavered in its representations to me and to others at John Hancock that ABT-773 was expected to have "once-a-day" or "QD" dosing and a "[c]onvenience, safety and tolerability profile competitive" with Zithromax, and that Abbott was developing "[o]ral suspension and I.V. forms" of ABT-773 that would "enabl[e] penetration into pediatrics and hospital segments."

109. Since the execution of the Research Funding Agreement, I have learned that Abbott's express representation in the Agreement that Abbott "expected" ABT-773 to have "once-a-day" dosing and a "[c]onvenience, safety and tolerability profile competitive" with Zithromax, as well as various other representations that Abbott made to Hancock in the Agreement regarding the prospects and condition of ABT-773, were materially false and/or

incomplete. Material facts that Abbott either misrepresented or failed to disclose to me and to others at John Hancock include the following:

(a) Although not referenced anywhere in the Agreement, Abbott had significant, unresolved issues concerning the safety of ABT-773 as of March 2001, particularly with respect to the potential for abnormal heartbeat prolongation (also known as "QT" or "QTc" prolongation) and chemical-driven liver damage (also known as "hepatoxicity," "hepatotoxicity," "liver toxicity" or simply "liver tox") among clinical trial subjects who took the compound. I understand that Abbott already had seen some evidence of possible liver toxicity during preclinical testing and among Japanese patients in an early study of ABT-773 conducted in Hawaii. Moreover, I understand that, "despite significant issues with the quality of the QT data collection to date," senior Abbott personnel working on the development of ABT-773 internally recognized by early 2001 that a "QT signal has emerged from both the pre-clinical and clinical programs" sufficient "to establish that there probably is an issue…."; (*See* PL's IN, IO, IP, IW attached);

(b) Abbott personnel had discussions concerning ABT-773 with representatives of the FDA in late 2000 in which the FDA described "hepatotoxicity and QT changes" as the "two primary toxicities they are worried about with macrolides and ketolides," and asked Abbott to undertake additional dog toxicology testing of ABT-773 focused specifically on those issues. I understand that, by February 2001, Abbott internally was describing "QTc Issues" and "Liver Toxicity Issues" as "Key Issues Facing the ABT-773 development program." I further

understand that both of these "Key Issues" remained unresolved when Abbott and John Hancock entered into the Agreement just one month later; (*See* PLs' IB, IC, ID, IE, IF attached);

(c) Abbott recognized well before the Agreement with John Hancock was signed in March 2001 that a "once-a-day formulation [of ABT-773] may not be possible based on the short half-life of the drug and the apparent short absorption window in the GI tract." I understand that, in June 2000, Abbott internal documents described "[u]ncertainty in ABT-773 convenience profile *i.e.* potential for [twice-a-day] dosing" as one of the "Key Commercial Issues" facing ABT-773; (*See* PLs' HS, HW attached);

(d) Although Abbott represented to John Hancock in the Agreement that the dosing of ABT-773 was "expected to be once-a-day," Abbott had concluded one month earlier that 300 mg, once-a-day dosing of ABT-773 "was not viable" for any indication "due to high levels of diarrhea (10-20%) and taste perversion (10-20%)," and still needed data from an ongoing Phase III trial before it could determine whether 150 mg, once-a-day dosing might be viable for two of the four target indications; CAP (community acquired pneumonia) and sinusitis (chronic sinus infection). I understand that Abbott simultaneously recognized that the "[a]bsence of consistent QD dosing for all indications" presented "a significant commercial hurdle" for ABT-773 in the United States; (*See* Ex. 32 and PLs' IN, IP attached);

(e) Abbott knew, prior to March 2001, that the development of a pediatric oral-suspension formulation of ABT-773 would be "very difficult" because taste tests

showed the compound to be "5 to 7 times more bitter than clarithromycin," another antibiotic that Abbott already marketed under the trade name Biaxin®. I understand that Abbott further knew that its inability to develop a pediatric formulation of ABT-773 could pose a significant regulatory hurdle for that compound in the United States because of FDA rules; (*See* PLs' IN, IO, IP, IQ attached); and

(f) Notwithstanding, Abbott's entire pediatric oral suspension program for ABT-773 was "on hold" and unfunded as of early 2001. (*See* PLs' IO, IQ attached).

110. I understand that the material information concerning the prospects and condition of ABT-773 that Abbott misrepresented or failed to disclose to me and to others at John Hancock in the Agreement played an important role in the subsequent decision of Abbott's Pharmaceutical Executive Committee ("PEC") to recommend in early December 2001, less than nine months after the Agreement was executed, that Abbott's entire ABT-773 development project "be put on hold," and that Abbott make efforts to "aggressively pursue out-licensing or selling the compound." (*See* Ex. 28 attached).

111. None of the facts set forth in Paragraph 109 of this Affidavit was disclosed to me or, based on my observations, to others at John Hancock either in the Research Funding Agreement or otherwise before I executed that Agreement on Hancock's behalf.

112. The true prospects and condition of ABT-773 as of March 13, 2001 was information material to my decision and, based on my observations, the decision of others at John Hancock to recommend and to enter into the Agreement with Abbott on the terms stated therein.

113. Had Abbott informed me or others at John Hancock of the true prospects and condition of ABT-773 as of March 13, 2001, as set forth, *inter alia*, in Paragraph 109 of this Affidavit, that information would have significantly and adversely altered the economics and attractiveness of the proposed funding deal from John Hancock's perspective. It would have dramatically reduced John Hancock's expected return and dramatically increased Hancock's risk of total loss. It also would have indicated that there was a significant risk that ABT-773, even if eventually successful, would be substantially delayed and, therefore, less valuable to John Hancock. I believe that, in such circumstances, I would not have recommended entering into that Agreement in its present form or, more likely, that I ultimately would not have recommended that John Hancock enter into any funding agreement with Abbott at all.

114. For example, if Mr. Deemer or Dr. Leonard had notified me on or prior to March 13, 2001, that Abbott had significant, unresolved issues concerning the safety of ABT-773 as of March 2001 (particularly with respect to the potential for abnormal heartbeat prolongation and liver toxicity among clinical trial subjects who took the compound), that the FDA was sufficiently concerned about these issues to ask Abbott to perform additional animal toxicity testing of ABT-773, or that Abbott already had determined that once-a-day dosing of ABT-773 might not be viable for some or all of its intended indications, I am confident that I would not have signed the present Agreement, which includes ABT-773, on that date. As previously stated, John Hancock had no interest in investing millions of dollars in compounds that already had been discontinued by Abbott, or that Abbott knew or had reason to believe would be discontinued shortly.

115. If I had ceased to recommend that John Hancock enter into the proposed Agreement with Abbott at any time on or prior to March 13, 2001, on account of any actual or

perceived problems concerning the condition of, or prospects for, ABT-773, I am confident that that Agreement would not have gone forward.

116. On or about December 20, 2001, I had a conference call with Thomas Lyons, the Controller of Abbott's Global Pharmaceutical Research and Development Division, and I believe others at Abbott for the purpose of obtaining an update regarding the status of the various Program Compounds. At no time during that conference call (or thereafter) did Mr. Lyons or any other Abbott representative disclose to me that Abbott's PEC had voted, less than two weeks earlier, to recommend that Abbott's entire ABT-773 development project "be put on hold," and that Abbott make efforts to "aggressively pursue out-licensing or selling the compound."

117. On or about December 26, 2001, I received a copy of Abbott's 2001 Program Status Report pursuant to Section 2.5 of the Agreement. A true and accurate copy of that Program Status Report with a cover letter from Mr. Lyons, dated December 18, 2001, is attached hereto as PLs' MZ. Nowhere in that 2001 Program Status Report did Abbott disclose to me that Abbott's PEC had voted, less than two weeks earlier, to recommend that Abbott's entire ABT-773 development project "be put on hold," and that Abbott make efforts to "aggressively pursue out-licensing or selling the compound."

118. Abbott never formally notified me or, based on my observations, anyone else at John Hancock of its decision to terminate ABT-773 as Abbott had done in the past with ABT-518 and ABT-594. I believe that I first learned of that decision in the course of a conference call with Abbott personnel in or about July 2002.

Abbott's Misrepresentations and Fraud
Concerning Its Intended and Reasonably Expected Spending

119. Section 2.2 of the Agreement requires Abbott, *inter alia*, to provide John Hancock, at least forty-five days (45) prior to the start of each Program Year, with a written ARP that spells out Abbott's expected Research Program expenditures on qualified research and development expenses (defined in Section 1.43 of the Agreement as "Program Related Costs") for that year and for each year remaining in the four-year "Program Term."

120. If Abbott's ARP for any given year did not "reasonably demonstrate [Abbott's] … intent and reasonable expectation to expend on Program Related Costs during the Program Term an amount in excess of the Aggregate Spending Target" as set forth in the Agreement (*i.e.*, $614 million), then John Hancock's "obligation to make any remaining Program Payments for any succeeding Program Years" automatically would terminate pursuant to Section 3.4(iv) of the Agreement.

121. At various points in time, Abbott provided me and others at John Hancock with documents that purported to set forth Abbott's "intended and reasonably expected" spending on the Program Compounds, including Abbott's ARPs for the First (2001), Second (2002), Third (2003) and Fourth (2004) Program Years. True and accurate copies of those ARPS are attached hereto as Ex. 32, 34 and PLs' MX, NK, and NO.

122. I and, based on my observations, others at John Hancock actually relied on the "intended and reasonably expected" spending information contained in Abbott's various ARPs for the purpose of administering Hancock's payment obligations under the Agreement. For example, I examined and relied upon Abbott's representations regarding its "intended and reasonably expected" spending on the Program Compounds contained in Abbott's ARP for

2002 in subsequently concluding that John Hancock was obligated to make its Second Program Payment in the amount of $54 million to Abbott in January 2003.

123. Since the execution of the Research Funding Agreement, I have learned that Abbott misrepresented its "intended and reasonably expected" expenditures on Program Related Costs in ARPs that it provided to me and to others John Hancock, including its ARP for 2002. I understand that the Research Program cost projections that Abbott has provided to John Hancock in its various ARPs reflect Abbott's "nominal" spending, as opposed to its "expected" spending. I further understand that, at all relevant times, Abbott's actual "intended and reasonably expected" spending on Program Related Costs was considerably less than the amounts communicated to me and others at John Hancock in Abbott's various ARPs, including its ARP for 2002.

124. Had Abbott informed me and others of its actual "intended and reasonably expected" spending plans on Program Related Costs in its various ARPs as required under the terms of the Agreement, including in its ARP for 2002, I believe that John Hancock quite possibly would not have been required to make, and I believe Hancock quite possibly would not have made, its Second Program Payment in the amount of $54,000,000 in January 2003.

John Hancock's Right to Receive a Partial Refund of Its Program Payments Based Upon Abbott's Failure to Spend the Entire Aggregate Carryover Amount

125. In the Research Funding Agreement, Abbott agreed to spend a minimum of $614 million (the "Aggregate Spending Target") on Program Related Costs over the four-year Program Term.

126. Under Sections 1.18, 1.44 and 1.45 of the Research Funding Agreement, the "Program Term" commenced on the "Execution Date" of the Agreement (*i.e.*, March 13, 2001), and ended four "Program Years" later on December 31, 2004.

127. Section 3.3(b) of the Agreement provides that,

> [i]f Abbott does not expend on Program Related Costs the full amount of the Aggregate Spending Target during the Program Term, Abbott will expend the difference between its expenditures for Program Related Costs during the Program Term and the Aggregate Spending Target (the "Aggregate Carryover Amount") on Program Related Costs during the subsequent year commencing immediately after the end of the Program Term. If Abbott does not spend the Aggregate Carryover Amount on Program Related Costs during such subsequent year, Abbott will pay to John Hancock one-third of the Aggregate Carryover Amount that remains unspent by Abbott, within thirty (30) days after the end of such subsequent year.

128. The "subsequent year commencing immediately after the end of the Program Term" was the calendar year ending on December 31, 2005.

129. Section 2.5 of the Agreement further provides, in relevant part, that,

> Abbott shall, no later than thirty (30) days before the last day of each Program Year, provide John Hancock with a reasonably detailed report setting forth the status of the Research Program and all Program Related Costs expended by Abbott during such Program Year.

130. At various points in time, Abbott provided me and others at John Hancock, pursuant to Section 2.5 of the Agreement, with documents purporting to be Abbott's "Program

Status Reports" for the various Program Years, including Abbott's Program Status Reports for the First (2001), Second (2002), Third (2003), Fourth (2004), Fifth (2005), Sixth (2006) and Seventh (2007) Program Years. True and accurate copies of those Program Status Reports are attached hereto as Ex. 43 and PLs' MZ, NK, NN, OZ, PC, and RU.

131. I understand from the various Program Status Reports that Abbott provided to me and others at John Hancock, as well as from Abbott's sworn interrogatory responses in this action, that Abbott did not spend the Aggregate Spending Target on Program Related Costs over the four-year Program Term. I further understand, based upon the same sources, that Abbott did not spend the entire Aggregate Carryover Amount in 2005 (*i.e.*, the "subsequent year commencing immediately after the end of the Program Term").

132. Notwithstanding these facts, Abbott has failed to refund to John Hancock one-third of the unspent Aggregate Carryover Amount as required under Section 3.3(b) of the Agreement.

Abbott's Obstruction of John Hancock's
Attempt to Audit Abbott's Compliance with the Agreement

133. Section 2.5 of the Research Funding Agreement provides, in relevant part, that,

> Abbott shall, and shall cause each Subcontractor to, maintain complete and accurate records … for purposes of demonstrating compliance with the terms hereof, that fully and properly reflect all work done, results achieved and Program Related Costs expended in performance of the Research Program. The books and records of Abbott and each Subcontractor related to the Research Program … shall be subject to copying, inspection and audit by (and at the expense of) John Hancock at any time and from time to time. Such audit shall occur on reasonable notice and during normal business hours by an independent auditor selected by John Hancock and reasonably acceptable to Abbott.… In the event that such audit reveals any material breach of Abbott's responsibilities hereunder, Abbott shall (i) pay the

> reasonable fees and expenses charged by such auditor, and (ii) fully and promptly cure such breach.

134. In or about late 2003, I became concerned that Abbott was not complying with all of its obligations to John Hancock under the Agreement. Specifically, I had suspicions that Abbott may have intentionally withheld or misrepresented material facts concerning at least one Program Compound in the Agreement or prior to its execution.

135. When I raised my concerns regarding Abbott's conduct with James Tyree, then Abbott's Vice President of Global Licensing and New Business Development, Mr. Tyree vehemently denied any violations of the Agreement or intentional misconduct on Abbott's part. Mr. Tyree specifically told me, in part, that "Abbott takes any allegations of fraud very seriously and, after investigating the matter, has concluded that no basis exists for any such allegation by John Hancock." A true and accurate copy of Mr. Tyree's denial letter to me, dated November 20, 2003, is attached hereto as PLs' RQ.

136. In the face of Mr. Tyree's unequivocal denial of any wrongdoing on Abbott's part, I did not wish to assert a legal claim against Abbott for misrepresentation or fraud unless and until I was reasonably sure that a sufficient factual basis for such claims existed. Accordingly, I and others at John Hancock ultimately decided to exercise Hancock's right under Section 2.5 of the Research Funding Agreement to audit Abbott's compliance with the terms of that Agreement prior to asserting any claim for misrepresentation or fraud. It was my hope and expectation that the information obtained through such an audit would allow me and others at John Hancock to either confirm or dispel our suspicions regarding Abbott's conduct.

137. On April 12, 2004, I sent a letter to Mr. Tyree at Abbott notifying him of John Hancock's intention to undertake an audit of Abbott's compliance with the Agreement pursuant

to Section 2.5, and identifying The StoneTurn Group ("StoneTurn") as John Hancock's chosen independent auditor. A true and accurate copy of my notification letter to Mr. Tyree, dated April 12, 2004, is attached hereto as PLs' NO. I included with my letter to Mr. Tyree a written description of the specific books and records related to the Research Program that John Hancock wished to examine in the first instance, along with a request that the materials be made available for examination by representatives of StoneTurn within thirty (30) days.

138. John Hancock's attempt to independently audit Abbott's compliance with the Research Funding Agreement ultimately was effectively stymied by Abbott. I understand and observed that Abbott responded to John Hancock's demand for an audit of Abbott's books and records pursuant to Section 2.5 of the Agreement by engaging in a protracted campaign to hinder, delay and obstruct Hancock and StoneTurn's efforts to examine and assess Abbott's compliance with terms of the Agreement.

139. On March 22, 2005, Abbott notified StoneTurn that Abbott purportedly had fulfilled its obligations with respect to John Hancock's compliance audit, and that Abbott would not respond to any further requests from, or make any additional documents or information available to, Hancock or StoneTurn.

140. As a result of Abbott's obstruction of John Hancock and StoneTurn's efforts to audit Abbott's compliance with the terms of the Agreement, Abbott never provided all of the documentation and information that was necessary for StoneTurn to complete its compliance audit on Hancock's behalf.

141. As a result of Abbott's obstruction of John Hancock and StoneTurn's efforts to audit Abbott's compliance with the terms of the Agreement, I and others at John Hancock were

unable to utilize the results of the audit process as an effective means to confirm or dispel our suspicions regarding Abbott's conduct.

142. The estimate of fees and expenses that John Hancock incurred and paid in connection with its failed compliance audit of Abbott is $330 thousand, which sum includes StoneTurn's fees and expenses, as well as the legal fees and expenses of Choate, Hall & Stewart personnel associated with their unsuccessful attempts to administer and obtain Abbott's cooperation with the audit.

Abbott's Failure to Maximize the Value of ABT-518 and ABT-594

143. Section 4.3(d)(i) of the Research Funding Agreement requires that, if Abbott ceases development of any Program Compound, "as soon as is practicable Abbott shall maximize the commercial value, if any, of the Ceased Compound to both parties by out-licensing or divesting such Ceased Compound to a third party." Section 4.3(d)(iii) further provides that Abbott thereafter shall,

> remunerate John Hancock based on sales of such Ceased Compound by the third party that has acquired or licensed the Ceased Compound … in a manner most consistent with the allocation that would have applied hereunder had such Ceased Compound not been so out-licensed or divested.…

144. I and others representing John Hancock demanded during negotiations that Abbott include the language Section 4.3(d) in the Agreement in order to ensure that, if Abbott decided to cease the development of any of the Program Compounds, Abbott would not simply put those compounds "on the shelf" and fail to out-license them because of their potential to compete with other compounds that Abbott was developing, or hoped to develop. I wanted Abbott's commitment that it would out-license or divest itself of each and every "Ceased

Compound" so that John Hancock could maximize its chances of at least recouping some or all of its investment in those compounds.

145. Abbott substantially ceased developing ABT-518 in 2001. Accordingly, ABT-518 is a "Ceased Compound" for purposes of Section 4.3(d) of the Agreement.

146. In the more than six years since 2001, Abbott has not out-licensed or divested ABT-518 to a third party.

147. Abbott substantially ceased developing ABT-594 in 2001. Accordingly, ABT-594 is a "Ceased Compound" for purposes of Section 4.3(d) of the Agreement.

148. In the more than six years since 2001, Abbott has not out-licensed or divested ABT-594 to a third party.

149. As a result of Abbott's failure to out-license or divest ABT-518 and/or ABT-594 to one or more third parties as required under the terms of the Agreement, John Hancock has not been able to recoup any of its investment in those compounds or otherwise maximize the value of that investment.

150. As a result of Abbott's failure to out-license or divest ABT-518 and/or ABT-594 to one or more third parties as required under the terms of the Agreement, John Hancock has not received any royalties or milestone payments for those compounds provided in that Agreement.

John Hancock's Damages

151. I believe that Abbott's breaches of the Agreement and fraud are of such a nature and of such importance that the Agreement would not have been made without them.

152. I believe that John Hancock has suffered actual monetary damages as a result of Abbott's breaches of the Agreement and fraud, including, but not limited to: lost or diminished potential royalties and milestone payments from Abbott on ABT-518, ABT-594 and ABT-773; lost or diminished potential royalties and milestone payments from any potential out-licensee of ABT-518 or ABT-594; the loss of Hancock's one-third share of the unspent portion of the Aggregate Carryover Amount; the loss of John Hancock's unnecessary Second Program Payment of $54 million; and the professional and legal fees and expenses paid by Hancock in its failed attempt to audit Abbott's compliance with the Agreement.

153. I have examined the Amended Report of John Hancock's damages expert, Mr. Alan Friedman of CRA International, and believe that Mr. Friedman has properly calculated John Hancock's damages with reasonable certainty using reliable principles and methods applied reliably to sufficient facts and data.

Authentication of Additional Exhibits

154. The documents attached hereto as PLs' KQ, LF, LG, OC, OW, PM, PY, PZ, and QQ are true and accurate copies of records from the files of John Hancock that were made at or near the time of the matter recorded therein by me or by other people at Hancock having knowledge of the facts recorded, and that were made and are kept in the normal course of Hancock's regularly conducted business activities consist with Hancock's regular business practices.

Signed under the pains and penalties of perjury this 28th day of January, 2008.

/s/ Stephen J. Blewitt
Stephen J. Blewitt

CERTIFICATE OF SERVICE

I hereby certify that this document is being filed with the Court through the ECF system and that a copy will be sent electronically to counsel for defendant through the ECF system on January 28, 2008.

/s/ Richard C. Abati
Richard C. Abati (BBO No. 651037)

4294625v1

PLs' CE

June 2000
ABT-594 Project Status Report

Monthly Highlights

- Experimental placebo manufacturing run prepared at PPD's Puerto Rico Manufacturing Plant (AHPI) in the Potent Drug Module. Special thanks to Serafin Torres and the API plant personnel, and PARD team members Rhonda Peck, Erskine Hilyer and Ji Zhou for their commitment and long hours!
- Enrollment in M99-114 is slower than planned and is under scrutiny by team personnel. (See July Progress Gauges below.)

Key Progress Gauges - June Accomplishments	Target Date	Status
• Begin testing for release and stability initiation of the 3 NDA lots of drug substance	6/5	Incomplete – Delay due to specification system issues (see below) Revised Target: 7/21
• Issue new drug substance test document	6/5	Incomplete – Delay due to issues surrounding new specification documentation system. Revised Target: 7/21
• Complete Development Plan preparation meetings	6/16	Complete
• 90 patients enrolled M99-114	6/25	Incomplete – 73 enrolled as of 6/30
• 2/3 of sites actively enrolling patients M99-114	6/25	Incomplete – 18 / 29 sites actively enrolling, 24 / 29 sites actively screening
• Obtain validated results for ICH Category 1 solvent DCE in 594 clinical drug substance lots and starting material	6/25	In Process
• Discovery Project Team to identify 3 potential follow-on compounds for advanced preclinical characterization	6/30	Complete
• Develop cholinergic channel modulator scientific franchise strategy	6/30	Complete
• Complete preparation for experimental capsule manufacturing run at AHPI (8/00) to assess environmental/employee exposure	6/30	Complete

July Projections	Target Date	Status
• Contact all M99-114 investigators to determine enrollment obstacles	7/5	
• Review early terminations and Adverse Event profile to determine strategic options to address slow enrollment	7/12	
• Finalize recommendations and initiate recommended strategies	7/21	
• Issue new drug substance test document	7/21	
• Begin testing for release and stability initiation of the 3 NDA lots of drug substance	7/21	
• 90 patients enrolled M99-114	7/31	
• Schedule active capsule experimental manufacturing run at AHPI for 8/00	7/31	

Key Issues/Decisions/Events

Area	Issue/Decision/Event	Progress
Venture	Project Milestone (GO/NO GO) was achieved on largel.	Data from Phase II studies were presented at Portfolio Review (October 6, 1999). The project team recommendations were supported: • Establish a maximum tolerated dose of the hard gelatin capsule (HGC) dosage form. • Continue with Phase IIB at higher doses.
PARD	75 µg HGC will be made for Phase IIB. Higher capsule strengths may be required.	Hard gelatin capsule (HGC) has been chosen as the Phase IIB/III formulation. In order to start Phase III in 3Q/2001, Phase III formulation process optimization started 5/00, includes potential degradation reduction, improved dissolution and enhanced mechanical encapsulation process. Some bias noted in assay method. Detailed investigation resulted in a change to the assay sample preparation to resolve the bias. PPD's Puerto Rico facility (AHPI) is being made ready for production. All required bulk drug product is approved and on stability. Manufacture of a placebo run in the AHPI high potency drug module was completed 6/00 in preparation for the planned manufacture of active capsules with personnel using personal protective equipment 08/00.
CAPD	We are at risk for possible increases in the cost of drug substance because we are dependent on other vendors to manufacture ABT-594 drug substance. Toxicology has recommended an impurity limit for mesylate needs to be set below the level of detection (LOD 0.002 & LOQ 0.005). A recrystallization procedure will be needed. Additional process work may be needed depending upon the outcome of the recrystallization process.	Abbott cannot manufacture highly potent compounds. CAPD has identified several potential vendors for the drug substance: Sicor, Chemsyn and Catalytica. Chemsyn has been selected as the manufacturer of the bulk drug substance. Three registration lots totaling 16 Kg have been completed at Chemsyn. A meeting to discuss setting the mesylate impurity limit was held on September 30, 1999. A specification set below the current limit of detection was advised by toxicology. CMC technical committee meeting held 1/6/00 to discuss mesylate specifications. Recommendations made. Mesylate specification at target: not more than 0.005% will be incorporated into Standard Control Procedure. Development of a recrystallization process of the current method has started. This should be incorporated into the process for the registration lots. All 3 registration lots recrystallized. All below 0.005% mesylate. Will begin testing for release and stability initiation of the 3 NDA lots of drug substance. Replacement Step 4 (Mitsunobu) chemical synthesis to eliminate mesylate going well in lab. Continuing analytical scrutiny for low level impurities in final drug substance. Determination to proceed with implementation of replacement Step 4 under evaluation.
NPD	If ABT-594 is scheduled, the NPV is significantly reduced.	An expert advisory meeting took place 11/98. The advisors felt it was unlikely that ABT-594 would be scheduled and recommended that we conduct several preclinical/clinical studies when a GO decision is made for Phase III development.

June 2000
ABT-594 Project Status Report

Area	Issue/Decision/Event	Progress
Toxicology	6-month rat study finding may suggest future possible occurrence of hepatocellular neoplasms in long term toxicology studies. If higher doses (>75 μg BID) are used in future clinical studies and registration purposes, another rat CA study using higher doses will need to be initiated.	No adenomas have been found in the study. Early deaths in the 2-year carcinogenicity study will be closely monitored. No further studies are recommended at this time. Justification for current dose selection in rat CA studies submitted to FDA 1/25/00. Received concurrence from FDA Carcinogenicity Assessment Committee. No need to perform additional carcinogenicity studies w/ABT-594.
Patent	Follow-on compounds discovered using human recombinant nAChR proprietary technology present increased risk.	Efforts initiated in March, 1999 to negotiate with SIBIA for the rights to use the human recombinant neuronal nicotinic receptor constructs as a screening tool have been terminated due to subsequent exclusive licensing for a period of three years of this technology by SIBIA to Eli Lilly. Merck has subsequently assumed control of SIBIA. To minimize risk associated with the use of the human clonal cell lines, Abbott has initiated a strategy of using only human subtype combinations not currently covered by existing issued US patents. Also, Abbott has initiated a strategy to concurrently pursue the cloning and expression of non-human nAChRs that fall outside the scope of SIBIA's patent estate. Cloning of the ferret α4, α3, β2, and β4 subunits is proceeding. Current results suggest that the homology between ferret and human is higher than between rat and human, and is >90% in the highly conserved membrane spanning and ligand binding domains, but that overall homology will likely be less than 90%. It is anticipated that the first of the ferret nAChR subtypes (α4β2) will be completed by 1Q/00. To expand compound libraries and identify novel structural classes, Abbott has partnered with Neurosearch. First joint research council meeting with Neurosearch held 1/31-2/1/00. One compound identified that appears to be 4-fold better based on Chung model vs. emesis model. Evaluating potential anti-depressant compound from this class. Three to five compounds to be chosen as follow-on to ABT-594 by May 2000. Of these 3-5 compounds, one will be chosen in July/Aug for Q4 2000 DDC.

June 2000
ABT-594 Project Status Report

Project Cost Summary - June

$000's Activity	Cumulative through 1999	YTD Actual	Projected Year-end	Current Funded Year-end	Variance	Cumulative to NDA
Clinical Program	22.9	4.1	8.4	8.4	0	157.1
CMC (PARD & SPD)	13.0	1.7	2.7	2.4	-.3	27.6
Drug Safety	8.7	1.5	2.4	2.9	.5	18.3
Other Support Costs	0.7	.4	.9	1.3	.4	12.2
Total	50.5	7.7	14.4	15.0	.6	215.2

File NDA = 5/2003

* Clinical program = grants, data mgt/stats, venture management, drug supplies

** Other Support Costs = Regulatory Affairs, RQA, Medical Services, Phase 1, RIC, Int'l MP, Invest. Drug QA, Discovery, Project Services

Clinical Study Progress

Protocol # - Study Name	Start (1st Patient Dosed)	End (Last CRF In House)	Total R/OSS $000	Total Target Patients	Current Enrollment
M99-114 – A Randomized, Double-Blind, Placebo-Controlled Comparison of the Safety and Efficacy of ABT-594 to Placebo in Subjects with Painful Diabetic Polyneuropathy	04/00	12/00	3,000	320	73

June 2000
ABT-594 Project Status Report

Business Rationale

Date: June 2000
Franchise: Neuroscience
Venture: Analgesia

ABT #: ABT-594
Trade & Generic Name: TBD, TBD
Mechanism of Action: Cholinergic Channel Modulator (ChCM)

Indications: Neuropathic Pain
Chronic Pain (publication only)

Product Profile

Attribute	Date Defined	Probability*	Confirm Status	Share Impact
Not scheduled	12/1996	High	1Q04	High
Chronic nociceptive pain efficacy	10/1999	Medium	2Q01	High
Neuropathic pain claim	6/1999	Medium	2Q01	High
General pain claim Moderate to moderately severe pain	12/1996	N/A	N/A	High
No tolerance/dependence or withdrawal	9/1998	Medium	1Q03	High
Very few abnormal LFTs	9/1998	High	2Q01	High
Low nausea/vomiting at effective dose	6/1999	Medium	2Q01	High
Other safety OK	9/1998	Medium	2Q01/1Q03	High
No differential efficacy (nicotine users vs non users)	9/1998	High	2Q01/1Q03	High
No differential side effect profile (nicotine users vs non users)	9/1998	Medium	2Q01/1Q03	Medium
No reinitiation of cravings in ex-nicotine users	9/1998	N/A	N/A	Medium
Onset of action comparable to other therapies for chronic nociceptive pain	6/1999	Low	4Q01	Medium
Onset of action comparable to other therapies for neuropathic pain	6/1999	N/A	N/A	Medium
BID dosing	6/1999	High	2Q01	High
No major drug interactions	12/1996	High	1Q03	Medium
Titration of 2-5 days duration required to minimize nausea and vomiting at effective dose.	9/1999	Medium	1Q00	High

* Probability Key:
High = 70-100%
Medium = 30-69%
Low = 0-29%

Market Forecast

	PPCC/DDC 12/1996*	Plan as of 6/1998*	Current Revised 10/1999**
Patent Status:	10/2010 (est.)	10/2016 (est.)	10/2016 (est.)
NDA Filing:	12/1999 (acute) 6/2001 (chronic)	12/2001	5/2003
Ex-U.S. Filings:	Same as above – Eur N/A - Jpn	12/2001 - Eur 12/2003 - Jpn	Update Pending
Projected U.S. Launch:	12/2001 (acute) 12/2002 (chronic)	6/2003	5/2004
Projected ex-U.S. Launches:	Same as above – Eur N/A - Jpn	12/2003 - Eur 9/20/2004 - Jpn	Update Pending
Peak TRx Share, U.S.:	6.6% (patients)	5% (Rx)	20% (Neuropathic pain) 10% (Persistent Chronic Pain)
Peak TRx Share, ex-U.S.:	5.4% (patients)	5% (patients)	5% patients
Peak Sales, U.S.: ($MM)	$285	$618	$367
Peak Sales, ex-U.S.: ($MM)	$308	$310	Update Pending
Pre-Tax NPV @ 15%, ex-U.S.: ($MM)	$338	$305	Update Pending
After-Tax NPV @ 12.5%, U.S.: ($MM)	$412	$813	$296
Avg. daily dose	50 mg	200 mcg	150 µg
Target Drug Cost/kg at Launch	$2,500	$2,500	$2,500
SMM at Launch	94.8%	97.2%	98.6%
SMM at Year 5			

* Forecast based on general pain target indication
** Forecast based on neuropathic pain indication and published study in chronic pain

June 2000
ABT-594 Project Status Report

Project Overview

Metrics Dates

Description	Date
DDC Meeting	12/1996 (PPCC)
Start of first GLP animal tox study	2/1997
First dose in human (beg. Phase I)	7/1997
First dose in patient (beg. Phase II)	7/1998
First dose in Phase III	10/2001 (est.)
Last Patient/Last Visit	12/2002 (est.)
NDA Filing	5/2003 (est.)
NDA Approval	5/2004 (est.)
Europe (EMEA) Filing	5/2003 (est.)
Europe (EMEA) Approval	TBD
Japan Filing	12/2003 (est.)
Japan Approval	TBD

CAPD

Drug Substance Source/Lot #	KG	Plan 6/1999	Actual Date	Plan 6/1999 Projected Cost/kg*
D-45L	0.3 KG	3/1997	3/1997	$ 200,000
CAPD	5.6 KG	3/1997	3/1997	$ 175,000
SICOR	14.9 KG	2/1998	2/1998	$ 40,000
SICOR/CAPD	2.5 KG	8/1998	8/1998	$ 40,000
Chemsyn Pilot Lot	1.0 KG	5/1999	5/1999	$ 29,700
Chemsyn Mfg. Lot	10.0 KG	10/1999	Not manufactured	$ 29,700
Chemsyn NDA Lot #1	4.85 KG	10/1999	On Test	$ 29,700
Chemsyn NDA Lot #2	4.80 KG	10/1999	On Test	$ 29,700
Chemsyn NDA Lot #3	5.45 KG	10/1999	On Test	$ 29,700

* Target cost of drug substance at launch is $2,500/kg (Finished Product)

PARD

Activity	Plan 6/1999	Current Revised 6/00	Actual
Phase I Formulation (PIB)*	7/1997	7/1997	7/1997
Clinical Supplies (PIB) for Molar Extraction	7/1998	7/1998	7/1998
Phase II Formulation (SEC) for IND	7/1998	7/1998	7/1998
Clinical Supplies (SEC) Shipped (Osteoarthritis, Surgery, Neuropathy)	10/1998	10/1998	10/1998
Phase IIb / Formulation (HGC) for Bio Study	3/1999	3/1999	3/1999
Phase III Clinical Supplies Manufactured	9/1999	6/2001	TBD
NDA Lots (3) Completed	6/2000	12/2001	TBD
Completion of 1 Year Stability for NDA	7/2001	2/2003	TBD
Formulation Peer Review	10/2001	TBD	TBD

* Performed by IDC

Toxicology

Toxicology Activity	Plan Start 1999	Actual Start Date	Report Completed
Gene Toxicology	2/1997	9/1996	8/1997
Acute Studies	3/1997	4/1997	8/1997
1 Month Rat/Monkey	2/1997	2/1997	11/1997
3 Month Rat/Monkey	7/1997	6/1997	8/1998
3 Month Mouse MTD	10/1997	6/1997	10/1998
SEG I and SEG II	10/1997	7/1997	7/1998
SEG III Rat (post natal development)	–	1/1999	Ongoing
6 Month Rat	1/1998	3/1998	7/1999
1 Year Monkey	6/1998	6/1998	3/2000
Carcinogenicity (2 yr.) Rat	12/1998	9/1998	Ongoing
Carcinogenicity (2 yr.) Mouse	12/1998	11/1998	Ongoing

Clinical Study Progress

Protocol:	M99-114 – A Randomized, Double-Blind, Placebo-Controlled Comparison of the Safety and Efficacy of ABT-594 to Placebo in Subjects with Painful Diabetic Polyneuropathy
Objective:	The objective of this study is to compare the safety and analgesic efficacy of 150 µg, 225 µg, and 300 µg twice daily (BID) of ABT-594 to placebo in subjects who have painful distal symmetric diabetic polyneuropathy.
ABT-594 Doses:	150 µg, 225 µg, and 300 µg twice daily (BID)
Comparator Doses:	Placebo
Target Enrollment:	320
Target Cost:	$3 MM
Actual Cost:	TBD
Status:	Ongoing
Major Findings:	TBD

PLs' DC

Andrea Landsberg /LAKE/PPD/ABBOTT
10/03/2000 07:32 AM

To: Robert J Weiland/LAKE/PPD/ABBOTT@ABBOTT

cc: Rosemarie K Waleska/LAKE/PPD/ABBOTT@ABBOTT, Christopher J Silber/LAKE/PPRD/ABBOTT@ABBOTT, Bruce McCarthy/LAKE/PPRD/ABBOTT@ABBOTT, George W Carter/LAKE/PPRD/ABBOTT@ABBOTT, Mike Williams/LAKE/PPRD/ABBOTT@ABBOTT, James Sullivan/LAKE/PPRD/ABBOTT@ABBOTT, Larry L Lin/LAKE/PPD/ABBOTT@ABBOTT

bcc:

Subject: ABT 594/963 Purdue meeting

Bob,
As you, Rose and I had discussed, if we move forward to set up a presentation of information to Purdue, the following people could probably do the presenting on key topics

Preclinical ABT 594:	Jim Sullivan
Clinical ABT 594:	Bruce McCarthy
Preclinical and Clinical Plan ABT 963:	George Carter
Market Opportunity/Business Rationale:	Andrea Landsberg

If anyone has objections or would like to suggest alternate individuals, please feel free to do so

One final comment that I neglected to bring up yesterday: George and I have had a number of conversations regarding the meaning of 'co-development' and the potential impact on development costs and timelines. I think this needs to be the topic of a separate discussion so that we can clearly define 'co-development' on our terms prior to any negotiations with a partner. Of course, Chris and the analgesia venture's input would be key in this discussion

Andrea

Silber DEP. EX. NO. 23
FOR ID., AS OF 2-9-07 BC

PLs' DR

Bruce McCarthy /LAKE/PPRD/ABBOTT
11/22/2000 04:15 PM

To: David D Morris/LAKE/PPRD/ABBOTT@ABBOTT, James W Thomas/LAKE/PPRD/ABBOTT@ABBOTT, James Steck/LAKE/PPRD/ABBOTT@ABBOTT, David C Ross/LAKE/PPRD/ABBOTT@ABBOTT, Christopher J Silber/LAKE/PPRD/ABBOTT@ABBOTT, Marilyn J Collicott/LAKE/PPRD/ABBOTT@ABBOTT, Michael K Blamesen/LAKE/PPRD/ABBOTT@ABBOTT

cc:

bcc:

Subject: ABT-594 M99-114 Study Size Discussion

Here are some items for discussion at the upcoming ABT-594 M99-114 Study Size Discussion meeting (see meeting announcement below).

1. Brief review of basis for power calculations for M99-114 (we've done this before, so can be a quicky review, if appropriate)
2. Discuss effect of drop-outs on power
3. Review power associated with fewer than 320 patients enrolled (e.g. at 240, 80% power given that all doses have efficacy vs. power given that the doses are independent in terms of efficacy).
4. How are various statistical presentations of "dose-response" related to sample size?
5. Discuss the different perspectives in assessing the difference between a sample mean and population mean (e.g. under which goals would an assessment of confidence intervals be preferred vs hypothesis testing with "power calculations")-David...is this the correct way of articulating the issue?
6. What projections can we make about the effect of study size on statistical evaluations of adverse events (?similar discussion regarding confidence intervals and hypothesis testing/power calculations?)
7. Discuss implications for selecting specific sample sizes (with result of achieving or not achieving statistical significance): what will we do with various outcomes if we enroll 240 subjects, 320 subjects, other numbers of subjects?
8. Regulatory acceptability of M99-114 data as pivotal or supportive (based upon trial design, doses selected and statistical outcomes).

Please feel free to use the meeting to raise any other issues related to study size in addition to those listed above.

Thanks!

---------- Forwarded by Bruce McCarthy/LAKE/PPRD/ABBOTT on 11/22/2000 03:56 PM ----------

Calendar Entry

○ Appointment ● Invitation ○ Event ○ Reminder ○ Anniversary

Brief description:
ABT-594 M99-114 Study Size Discussion - Venture Conference Room - with Lunch

Date: 11/28/2000
Time: 12:00 PM - 01:00 PM

Detailed description:

Invitations have been sent to: David D Morris/LAKE/PPRD/ABBOTT, James W Thomas/LAKE/PPRD/ABBOTT, James Steck/LAKE/PPRD/ABBOTT, David C

CONFIDENTIAL
ABBT0109399

Thomas DEP. EX. NO. 18
FOR ID., AS OF 4/13/07
Ross

Ross/LAKE/PPRD/ABBOTT, Bruce McCarthy/LAKE/PPRD/ABBOTT, Christopher J Silber/LAKE/PPRD/ABBOTT, Marilyn J Collicott/LAKE/PPRD/ABBOTT, Michael K Blamesser/LAKE/PPRD/ABBOTT

Chairperson Nancy M Palbicke/LAKE/PPRD/ABBOTT
This meeting repeats starting on (if the date occurs on a weekend the meeting).

PLs' DW

CTM: John Schanzenbach **Project:** Abbott M99-114 **Date:** 12/13/00

Nov. Dec.

	Current Period (Planned)	(Actual)	(Variance)	Project to Date (Planned)	(Actual)	(Variance)	Next Period (Planned)
PSSVs completed	0	0	0	45	40	-5	0
# hours per visit	0	0	0	20	16.27	-3.73	0
SIVs completed	0	0	0	30	32	2	0
# hours per visit	0	0	0	20	25.5	5.5	0
IMVs completed	12	12	0	71	71	0	10
# hours per visit	32	30.56	-1.44	32	32.38	0.38	32
COVs completed	0	0	0	0	0	0	0
# hours per visit	0	0	0	0	0	0	0
Subjs screened	52	82	30	508	508	0	40
Subjs enrolled	30	34	4	244	244	0	20
Subjs completed	NA	24		NA	88		15
CRFs retrieved	NA	19		100	100	0	30
Billed services	47562.5	45709.89	-1852.61	504989.69	505531.9	542.20	37450
Billed expenses	10200	8386.43	-1813.57	124100	77400.28	-46699.72	8500
CTM hours billed	95	86	-9	1045	1226.25	181.25	60
PA hours billed	10	8.25	-1.75	374	75.25	-298.75	10
% Utilization Garrison	40	47	17.50%	40	47	17.50%	41
% Utilization Lentz	90	75	-16.67%	90	84	-6.67%	63

} projected actual

Other

Assessment of overall study status: ahead of schedule, on-time, behind schedule

Project continues to be on time.

Assessment of overall client relationship status: correct, productive, productive and cordial

We continue to have a good working realtionship with Abbott.

Next milestone payment due

250 CRFs received early to mid March

Project team turnover

None

Pending client/scope issues:

Study randomization to end on 1/5/01.

→ will prob. have ~270 randomized pts. by this date due to drop out rate, will not be able to reach 320 subjects for a valid study, may get safety data

Other early stage issues

None

Travel expenses per visit

482.00 per trip expenses

appears to be a shock to Marilyn Ollicott, had just transferred supplies from sites to more active sites.

last pt. visit ~ March 2/01

PLAINTIFF'S EXHIBIT tabbies DW

John doing estimates for remainder of study:

→ can probably complete study within estimated 120 INVs in original milestone ~~visit~~ payments

→ pro-rating milestone payments.
320 CRFs retrieved $72,000
320 pts. randomized $72,000

→ if this is realistic, really only need to negotiate project mngmt. for ~~2001~~ 2001, extra COVs
pro-rating

John needs to do estimates/projections > to KSS, LMO by COB Fri 12/15

total revenue
total expenses

to determine how we will do financially.

Kathy
→ should not pro-rate milestone payments, since based on # visits, not tied in to # pts.
→ still need add'l prog. mngmt. charges

PLs' IB

November 2000 - "Top" Issues

Key Issues/Decisions/Events

Area	Issue/Decision/Event	Progress
ABT-378 Kaletra Regulatory		
	Redacted	
ABT-492 Clinical		
ABT-518 Toxicology/ Metabolism	Key tox finding was hepatotoxicity in one-month rat study. *In-vitro* and *in-vivo* data indicate a potential for mechanism based drug interations.	The Phase I first-in-man protocol has been designed to address these issues. Additional tox and metabolism studies planned to address this issue.
ABT-594	USAN approval for the generic / chemical name for ABT-594 was received. The United States Adopted Name for ABT-594 (A-166594.47) is ebanicline tosylate (ē-ba-ni-klēn to-se-lāt.)	
ABT-627 Formulation Manufacturing	R.P.Scherer (Tampa) is a single site for production of drug product. Site audit revealed deficiencies which will delay production of Phase III clinical supplies but will NOT delay initiation of Phase III trials.	Alternate R.P. Scherer sites as well as alternate vendor options are being explored. Deficiencies are being corrected and will be resolved prior to production of Phase III clinical supplies in 1/01.
PARD	French authorities have raised issue of acid treated gelatin in our SGCs (also used in Kaletra and Norvir).	PARD will investigate alkaline treated SGCs for possible switch in the NDA runs.
ABT-773 Regulatory	An end of of Phase II meeting with FDA was targeted for the end of September/mid October timeframe, but rescheduled to the end of November at the request of FDA.	Meeting with FDA was held on November 27th. QT effects are the current hot topic for the FDA, and was reflected in the changes they requested to the Phase III program. They also requested an acute tox study in dog to further evaluate cardiac effects. The required "body of evidence" for obtaining a resistance claim for *s.pneumo* was discussed and the FDA recommendation included having an IV formulation to get bacteremic patients and more serious CAP infections.
	Regulatory uncertainties over how to deal with the ketolide/macrolide class regarding QT interval effects.	FDA concern is whether ketolides behave like macrolides and whether there may be a class effect. They also discussed whether a Phase I study should be conducted in subjects with

November 2000 - "Top" Issues

Key Issues/Decisions/Events

Area	Issue/Decision/Event	Progress
Venture / HPD	Obtain sufficient quantity of clinical isolates with resistant organisms to request a separate claim for activity against resistant *S. pneumoniae*.	underlying cardiac disease. They are requiring EKG monitoring in all Phase III studies. FDA feedback regarding a resistance claim for PRSP is that a sufficient "body of evidence" needs to be gathered to convince them to grant a claim. They estimate >10 resistance isolates will be required, CAP and ABECB isolate requirements need further clarification, but ABS isolates are evaluated separately. They are not convinced about the clinical significance of MRSP and need further evidence. They suggest that an IV formulation to obtain bacteremic patients and more severe CAP infections will enhance the probability of obtaining the claim.
	The initial development of an IV formulation has been completed and clinical supplies have been manufactured by HPD. Year 2001 funding was committed by HPD.	HPD funding for 2001 ($7MM) is no longer approved. At the ABT-773 Portfolio meeting, Jeff Leiden committed to find funding (approx. $1MM) to do the Phase I studies for the IV in 2001 to enable us to evaluate the viability of the formulation in terms of pain on injection and the dose requirements.
Japan	Due to the dose change in the base development program, Phase I will be repeated in Japan to further evaluate dose-ranging. An increase in liver enzymes was observed in the low and medium dose groups of Japanese volunteers in the first study in Hawaii, and will be further evaluated in the Phase I studies done in Japan. A Japanese dose and formulation, as well as the Phase II/III studies, will be defined once the dose-ranging has been completed. This plan will determine the filing date for Japan.	The Food Effect Phase I study was started November 25th and the Dose Ranging study will initiate December 14th. Once these results are available, we plan to meet with Kiko in May to discuss the Phase II/III program.
ABT-822 Project Timeline		

Redacted

ABT-963
Cox-2

PHARMACEUTICAL PRODUCTS RESEARCH & DEVELOPMENT
GLOBAL AI SPLIT
($MILLIONS)

Ongoing Development Programs	2000 APU Global	2000 APU Domestic	2000 AGU Global	2000 AGU Domestic	Key Unfunded Programs
NEUROLOGY					
Cholinergic Channel Modulator	15.0	...	14.4	...	8.0 A.
ANTI IFECTIVE					
Ketolide	74.1	...	67.1	...	5.7 B.
Quinolone	6.8	...	6.8	...	
UROLOGY/CARDIOLOGY					
HIV					
CANCER					
Endothelin	8.0	...	13.0	...	5.0 E.
Metalloprotease (MMPI)	5.0	...	5.0	...	...
Farnesyltransferase (FTI) #2	...	...	...	...	...
TSP #1	6.6	...	6.6	...	...
Anti-Mitotoc	3.0		6.0		
Other New Products					
Other					
Total Development					
Discovery					
Total PPD (Without Risk)					
Risk/Affordability					
Total PPD (With Risk)					
Total Global & Domestic					

Redacted

Pharmaceutical Products Research & Development

2000 Discovery Development Candidate (DDC) Target Dates
NOVEMBER 2000

PROJECT/COMPOUND	THERAPEUTIC TARGET	PROBABILITY	TARGETED REVIEW DATE CURRENT MONTH	PRIOR MONTH
Anti-Mitotic	Cancer	Complete	March 9	March 9
MMP1 2nd Generation	Cancer	Complete	March 9	March 9
Anti-Mitotic (7010)	Cancer	Complete	March 9	March 9
Quinolone (In-house)	Anti-infective	<25%	2Q01	December 15, 2000
NNR ABT-594 Backup	Pain	>50%	1Q01	December 7, 2000
TSP #2	Cancer	>25%	1Q01	4Q00

STATUS OF PAST CANDIDATES NOT FUNDED

THERAPEUTIC
Redacted

NOTE: CHANGES FROM PRIOR

PLs' IC

Belinda A Hightower /LAKE/PPRD/ABBOTT

11/20/2000 03:28 PM

To Phyllis L Kincaid/LAKE/PPRD/ABBOTT@ABBOTT

cc D44J, Cheryl D Spencer/LAKE/PPRD/ABBOTT@ABBOTT, Jeanne M Fox/LAKE/PPRD/ABBOTT@ABBOTT, Gregory Bosco/LAKE/PPRD/ABBOTT@ABBOTT

bcc

Subject Clinical Hold

I received a phone call from Carol Meyer (Anti-Infective) moments ago, informing me that a conference call was held with the FDA and the agency requested that they place the following ABT-773 studies on HOLD. The team is drafting a letter which will be faxed to each of the 80 sites (approx.) with a supplemental telephone call to instruct the sites not to enroll any additional subjects until further instructed. There are 8 subjects who have received drug and will remain in the study and followed during this interim period.

M00-219 (CAP)
M00-216 (ABECB)
M00-222 (Pharyngitis)
M00-225 (Sinusitis)

The team is scheduled to meet with the agency for an *End of Phase II* meeting on Monday (27 November, 2000) and will hopefully discover whether the HOLD is lifted.

Kind regards,
Belinda

PLs' LJ

Blewitt, Stephen

From: Philip Deemer [phil.deemer@abbott.com]
Sent: Friday, October 27, 2000 10:35 AM
To: Sblewitt@jhancock.com
Subject: ABT-980

Attached is the letter that was issued Wednesday to the clinical community regarding 980.

To: Kimberly C Smith/LAKE/PPRD/ABBOTT@ABBOTT
cc:
Subject: letter for US investigators 097,098,-989,-179 trials

October 25, 2000

Dear Investigator:

Re: Clinical Trials with ABT-980 (Fiduxosin) , alpha1 antagonist for the treatment of BPH.

In recent weeks, during routine laboratory monitoring of patients included in trials in the USA, Abbott Laboratories has received safety information that indicates the development of serum transaminase abnormalities exceeding three times the upper limit of normal in approximately 1.5 to 3 percent of patients taking ABT-980 for BPH.

Although, to date, these elevations improved and/or values returned to normal upon discontinuation of the drug, it is unlikely that a medication with this profile would offer patients advantages over current treatments. Therefore Abbott has decided to discontinue the clinical development program for ABT-980, effective immediately.

You will be contacted by the CRO or Abbott personnel in the coming days in order to make arrangements to close out the study.
You will be asked to contact your patients in the next few days, instructing them to discontinue drug treatment immediately and to present for a discontinuation assessment at your clinic, within seven days. The final visit procedures are itemized in the protocol. However please note the following deviations from the protocol with respect to the final visit: urinary flow assessment and patient questionnaire completion are no longer necessary, and the biliary ultrasound assessment may be completed within 30 days following the last dose of study drug, as opposed to within 48 hours. Should liver enzymes be elevated above 3 fold Upper Limit of Normal values, repeat profiles are to be determined at least weekly, until normalization of the values.

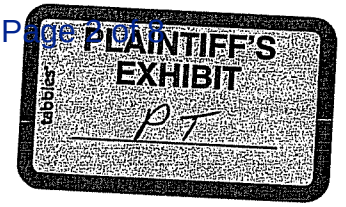
We want to thank you and your staff for your work and commitment to the ABT-980 clinical trial program, and we apologize for any inconvenience the program discontinuation may cause you and your patients.

Sincerely,

Marleen Verlinden, Ph.D.
Urology Venture Head
Abbott Laboratories

CONFIDENTIAL
JH 000778

PLs' PT



INITIAL PORTFOLIO PRIORITIZATION

C- continue
P- pending
T- terminate

Project	Priority	Next steps	Responsibility	Timing
Anti-infectives				
ABT-492	C	• Address safety issues (including QTc) with internal/ expert review • Determine how many indications at launch (pay back)	• J. Leonard	-
HSR-903	T	• Consider trading with Daiichi • Halt any new expenditure	• J. Tyree	-
ABT-773	C	• Assess side effects issues with expert review (QTc and liver tox.) • Ensure all drug interactions are adequately covered • Assess relative to Ketek	• J. Leonard • J. Leonard • I. Loew	-
Urology				
BSF 420627	P	• Set up task force to address issues and bring back plan to senior management – Reasons for failure of the SKB ETa/b antagonist – Design short (~4 week) PoP trial for symptom relief – Rationale for sustained release formulation – Nature of the Schwarz Pharma relationship	• J. Leonard	• By May
Hypothyroidism				
T3/T4	P	• Assess most appropriate ratio • Gain FDA feedback on study design • Determine ex-US market attractiveness (price)	• J. Leonard	• By May
Asthma				
Hokunalin tape	P	• Conduct market research on acceptance by different patient segments • Determine how to position against long acting beta agonists and combination inhalers • Evaluate opportunity to gain complete access to the patch technology	• A. Higgins/ E. Fiorentino • J. Tyree	• May

0 0

INITIAL PORTFOLIO PRIORITIZATION (CONTINUED)

C- continue
P- pending
T- terminate

Project	Priority	Next steps	Responsibility	Timing
Oncology				
ABT-510	C	• Pursue proof of concept • Leverage TAP knowledge of angiogenesis product development (appropriate endpoints)	• Project team	• As planned
ABT-751	C	• Pursue proof of concept • Use echocardiogram to monitor potential cardiotoxicity • Resolve potent drug manufacturing approach	• Project team • CMC group	• As planned
ABT-518	Hold/T	• Wait for May results from Pfizer (will save ~$1mill) and re-evaluate • Halt all further expenditure	• Senior management	• May
Rubitecan	P	• Significant clinical rework required (funded by partner)- further in-depth review required • Make a proceed decision when 2Q data available	• J. Leonard	• By May
Theragyn	P	• Negative initial scientific perspective - further in-depth review required, e.g., – Determine if there is a PoC to support claim – Address GMP issues – Determine best control to demonstrate efficacy • Re-look at partnership contract	• J. Leonard • J. Tyree	• By May • By May
ABT-627	C	• Seek alternative funding (e.g., NCI) before starting major trial • If move ahead – Determine how to ensure NDA filing in 2004 – Get FDA input since survival not primary endpoint – Harmonize US and EU study design and inputs • Consider partnership (e.g., BI or established oncology player)	• J. Leonard, P. Nisen • J. Tyree	• ASAP • By May

1 1

INITIAL PORTFOLIO PRIORITIZATION (CONTINUED)

C- continue
P- pending
T- terminate

Project	Priority	Next steps	Responsibility	Timing
Cardiology/ thrombosis				
Darusentan (LU 135252)	Hold/T	• Continue currently budgeted funding for next 6 months • Do not start any new trials (e.g., hypertension planned for May)	• Project team	• Ongoing
		• Consider out-license or swap	• J. Tyree	• ASAP
LU 208075	Hold/T	• Continue currently budgeted funding for next six months	• Project team	• ongoing
		• Look at Myogen deal • Out-license or swap	• J. Tyree	
Levosimendan	C	• Conduct detailed expert panel review for trial design	• J. Leonard	• May
PEG-hirudin	P	• Set up expert panel for commercial assessment (is diabetes an option?)	• E. Ogunro	• By May
Ancrod	T	• Identify out-licensing opportunities	• J. Tyree	• TBD
Urokinase	P	• Market research required on open cath • Match versus tPA in dose-ranging studies to determine efficacy	• E. Fiorentino	• By May
Pro-urokinase	C	• Identify opportunities to speed up program	• Project team	• TBD
Clivarine	C	• Assessment by HPD (review previous evaluation and new trial data)	• E. Ogunro	• By May
		• Understand finished product manufacturing cost	• B. Dempsey	
Rythmol SR	C	• Continue filing • Verify if package is likely approvable • Assess commercial attractiveness in a generic market	• Project team	• Ongoing

INITIAL PORTFOLIO PRIORITIZATION (CONTINUED)

C- continue
P- pending
T- terminate

Project	Priority	Next steps	Responsibility	Timing
Neuroscience				
ABT 594	P	• Await results from ongoing PII trial – probable T • Project team to develop decision criteria for go/no go	• Senior management	• June/ July
ABT 963	C	• Identify a co-development/co-promotion partner (TAP high on list) • Evaluate benefits of the long half life in pain and cancer (including additional physician market research) • Explore cancer prophylaxis and Alzheimer's indications	• J. Tyree • Project team	• TBD
BSF 201640	P	• Complete review of all schizophrenia NCEs with expert panel • Complete staffing of internal project team, but halt further expenditure beyond looking at hepatic tox. and QTc • Understand Novartis contract and level of interest	• I. Loew • Project team • J. Tyree	• By May
BSF 190555	P	• Complete review as above • Halt further expenditure pending outcome	• I. Loew	• As above
BSF 74398	C (no cost)	• Allow DevCo to continue development • Re-look at relationship with DevCo	• Project team • J. Tyree	• By May
Diluadid Oros	Hold/T	• Return to ALZA or out-license to other interested partner	• J. Tyree	• TBD
Hydrocodone	C	• Assess regulatory pathway • Understand DEA impact on manufacturing	• Project team	• By May
Bimoclomol (ABT 822)	P	• Await data from ongoing trial in April before deciding whether to continue - probable T • Halt further expenditure pending outcome	• Senior management	• April

INITIAL PORTFOLIO PRIORITIZATION (CONTINUED)

C- continue
P- pending
T- terminate

Project	Priority	Next steps	Responsibility	Timing
Gastro-enterology				
Ganaton	P	• Conduct U.S. commercial assessment with TAP	• E. Fiorentino	• By June
		• Assess how to position in Europe versus generics and implications for comparative trial		
		• Develop model to assess spend at different termination points	• Bob Funck	• By May
TU-199	T	• Terminate outside Japan	• Project team	• Immediate
AU-224	C	• Develop and pursue a small PoC trial in humans ASAP (consider niche indication first and leverage Marlene's expertise)	• Project team	• ASAP
		• Conduct market research on IBS versus constipation (including pricing)	• E. Fiorentino	
Immunology				
D2E7	C	• Conduct intensive product review – 2 day meeting with J. Lennard's group (already in process) – ½ day session with senior management group	• J. Leonard	• By May
		• Important actions include – Approach FDA for fast track and compassionate use – Develop strategy for DMARD claim in first submission – Assess need for Enbrel assay to detect HAHAs – Assess delivery device options – Evaluate additional indications (e.g., Psoriasis, Crohns, heart failure) and pediatric program – Profile Celltech product – Assess impact of additional IV program on reimbursement	• Various	• By May
		• Develop list of potential marketing partners for quids	• J. Tyree	

INITIAL PORTFOLIO PRIORITIZATION (CONTINUED)

C- continue
P- pending
T- terminate

Project	Priority	Next steps	Responsibility	Timing
Immunology ***(continued)***				
Segard	Hold	• Continue filing in EU and Canada • Put on hold in US – consider creating a small team in the US to analyse data, propose smaller PII study • Research pricing, marketing and Phase IV plans in Europe • Look at TNF-alpha levels retrospectively to see stratification with IL-6 • Assess manufacturing strategy • Identify potential out-licensing opportunities (Genentech)	• Project team • J. Leonard • J. Tyree	• Ongoing
J695	P	• Decide on most attractive indications from Abbott and partner perspective • Discuss with partner ways to share the various indications and potential for TNF-alpha combinations • Add commercial person to the project team by this week	• E. Fiorentino • J. Tyree • Ongoing	• ASAP

INITIAL PORTFOLIO PRIORITIZATION (CONTINUED)

C- continue
P- pending
T- terminate

Project	Priority	Next steps	Responsibility	Timing
PIV programs				
Clarithromycin	C	• None identified	-	-
Omnicef	C	• None identified	-	-
Kaletra	C	• None identified	-	-
Norvir	C	• None identified	-	-
Meridia	Hold	• Conduct commercial assessment for CNS and depression (P&L)	• B. Dempsey, J. Arnott, E. Fiorentino	• ASAP
		• Assess combination therapy with fibrates • Assess outcomes trial design to meet preferred commercial profile; determine payback	• Project team	
Uprima	C	• Ensure no redundant trials with TAP in Europe	• Project team	• Ongoing
Trandolapril patch	T	• Halt all activities	• Project team	• Immediate
Trandolapril "Invest" clinical program	P	• Review trial in more detail (reduce complexity and risk)	• E. Fiorentio	• By May
Other trandolapril trials	C	• Continue "Create", "Peace" and "Benedict" trial programs	• Project team	• Ongoing
Fenofibrate	C	• Develop co-formulation ideas with Meridia and statins (including assessment of sales and costs)	• Project team	-
Depakote	C	• None identified	-	-
Gengraf	C	• None identified	-	-